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# 2005 Annual Report

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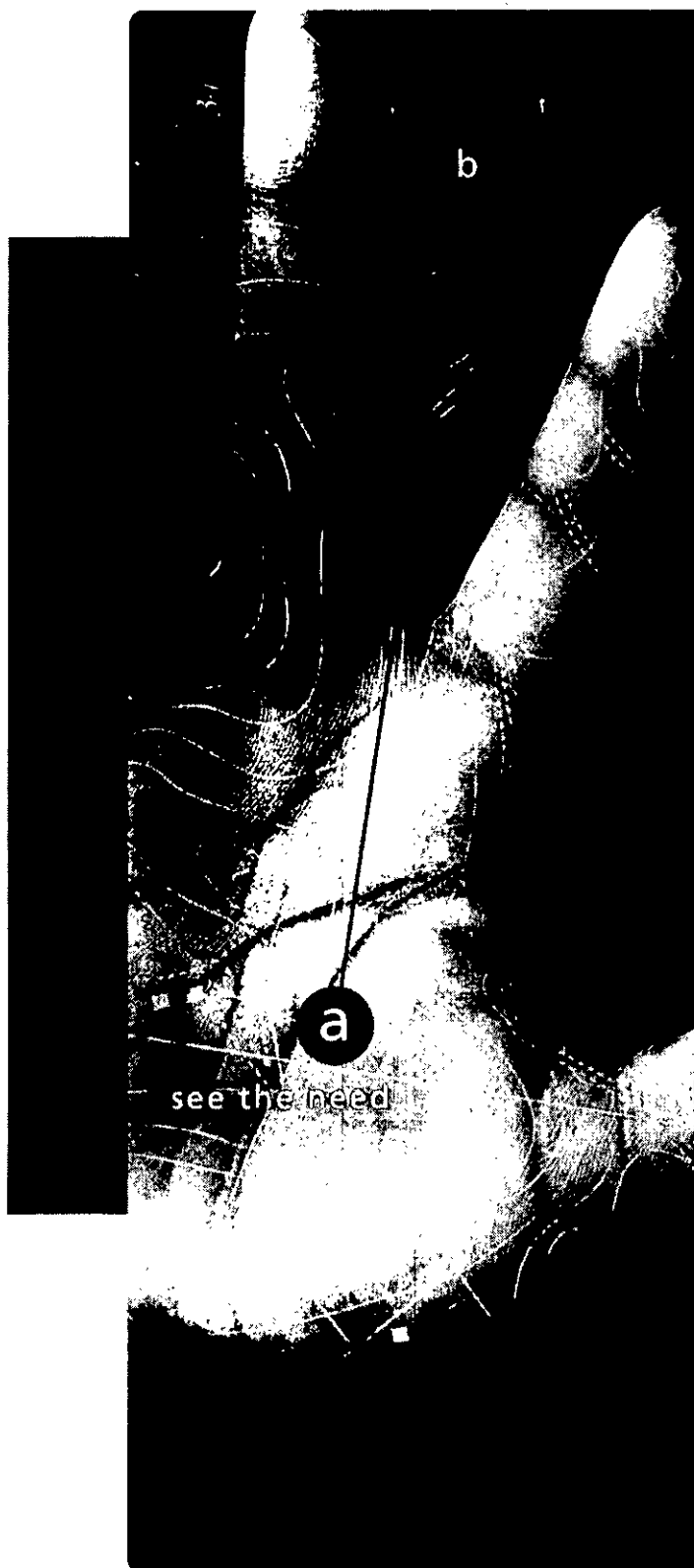
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Avigen



see the need

Avigen is committed to providing physicians and their patients with innovative therapeutics for the treatment of serious, chronic neurological conditions. What makes us unique is how we plan to get there. We are committed to exploring novel mechanisms that shorten the path to results. Not just different—positively different.

It begins with investigating and understanding the problem as never before. Once we know why, we can understand how. Our strategy is to develop and commercialize our products in North America and seek to out-license rights to develop and market our products outside the U.S. We will continue to look for promising drug candidates to expand and complement our product pipeline through a combination of internal research, acquisitions and in-licensing, with the goal of becoming a fully integrated pharmaceutical company.

**AV650**

For the treatment of disabling neuromuscular spasm and spasticity. AV650 is a centrally acting small molecule that we believe is non-sedating and which may treat and prevent recurrent, painful muscle spasms. We believe AV650, which is marketed by others in Europe and Asia, will lead to improved function, sleep uninterrupted by pain, and better quality of life overall.

**AV411**

For the treatment of neuropathic pain. AV411 is a small molecule with a new mechanism of action based on the theory that specialized cells in the nervous system known as "glial cells," rather than nerve cells, can mediate neurological pain states. We believe AV411, which is based on an approved drug currently marketed by others outside the U.S. for non-pain-related illness, is safe, long lasting, and non-addictive, and allows patients to preserve normal sensation with minimal side effects.

**AV513**

For the treatment of bleeding disorders, including hemophilia. AV513 may represent the first non-protein, non-gene therapy approach for the treatment of hemophilia, the first agent to treat multiple bleeding disorders, and the first treatment with the potential to be taken orally.

  
Avigen

The Direct Route from A to B.

## To Our Stockholders

We began last year with a clear mission – to build a sustainable business through the development and commercialization of differentiated drugs to treat chronic neurological conditions. We sought products that differentiate themselves, not just scientifically, but clinically and commercially. We sought products in large markets, but in indications with predictable clinical development timelines and modest capital investment requirements. We sought markets where Avigen could, with a small but concentrated sales force, launch the products independently in the U.S. And finally, we sought products, when possible, with reduced clinical development risk due to previous human experience.

Despite our demanding objectives, the dearth of viable product opportunities, and fierce competition, Avigen's team persevered and assembled an attractive pipeline through in-licensing and successful internal research. Our pipeline currently consists of three unique drug candidates that each strongly differentiate themselves from other drugs in their class and have the potential to become market leaders. With the strength of our balance sheet, we believe we have the resources to fund each of these product candidates to its next significant value inflection point.

Our lead drug candidate, AV650, offers the promise of a non-sedating product for the treatment of neuromuscular spasticity and painful muscle spasms. AV650 was in-licensed from our partner Sanochemia Pharmazeutika AG of Vienna, Austria. Because it has been marketed in parts of Europe for over 20 years, it comes to us with a wealth of human safety and efficacy experience. Our second drug candidate, AV411, is a first-in-class drug for the treatment of neuropathic pain with the potential for reduced CNS side effects. AV411 was internally identified as part of our research effort on glial modulation and its role in chronic neuropathic pain. AV411 is a marketed drug in Japan and Asia, although for a wholly different indication, and has a good human safety record at the prescribed doses. Our third drug candidate, AV513, is an oral drug for the treatment of multiple bleeding disorders, including hemophilia A and B. While not directly in line with Avigen's neurologic focus, AV513 is a unique asset with the potential to add substantial value to the company. It is a first-in-class molecule with the potential to revolutionize how hemophilia is treated by reducing or eliminating the need for multiple weekly intravenous injections.

During 2005, we took significant steps to preserve our financial resources through the reduction of our headcount and sublease of a significant portion of our operating facilities. In December, we also divested our gene therapy assets to Genzyme Corporation and received \$12 million in cash. We will also receive future milestones and royalties on Genzyme's successful development of the clinical program in Parkinson's Disease, as well as other programs that utilize the extensive intellectual property estate created by Avigen. As a result, we closed 2005 with approximately \$70 million in cash and investments and believe these resources will be able to fund our projected burn rate for approximately two to three years. However, recognizing the cyclic nature of the financial markets, we may seek strategic financing to expand our current pipeline.

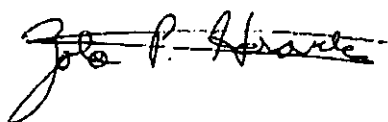
A significant part of our decision to leave gene therapy was the challenging economics for a company our size. Our current portfolio offers the advantage of a more efficient business model that allows us to leverage external resources and redirect capital that was previously invested in manufacturing staff and facilities directly into clinical development, resulting in a higher return on investment. In addition, because we are working with drugs that are manufactured and sold in other markets, we have been able to establish relationships with existing manufacturers of commercial-grade product. This will minimize lengthy and expensive process and formulation development, thereby shortening timelines and further streamlining our processes.

Having built an attractive pipeline and strong financial foundation, in 2006 we will focus on executing our ambitious clinical development plans. While we will remain open to opportunities to in-license other new compounds, we will focus on expanding the clinical and commercial utility of our current candidates, as well as developing next generation molecules with improved profiles.

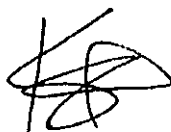
In 2005, we lost our Chairman of the Board, Philip Whitcome, to cancer. Phil was not only a mentor, but an inspiration to all of us at Avigen. While we no longer have his day-to-day counsel, we will never lose sight of his guiding *mantra* that our goal is not just to build a business, but a "sustainable business" – a vision that continues to drive us toward enduring long-term value, not transient short-term returns.

In last year's letter to our stockholders, we committed that 2005 would be "a year in which we establish Avigen as a company on its way to becoming a successful commercial enterprise." We believe we took a significant step toward achieving that goal and expect to build on that foundation in 2006.

On behalf of Avigen's Board of Directors and management, we thank our stockholders, partners and employees for their support and continued confidence.



Zola Horovitz, Ph.D.  
Chairman of the Board



Kenneth Chahine, Ph.D., J.D.  
President and Chief Executive Officer

*Forward-looking statements:*

*The statements made in this Annual Report regarding Avigen's plans and expectations for the future, including its expectations that its products have good safety profiles and will differentiate themselves from others in their class, its expectations for expanding the clinical and commercial utility of its current product candidates, its expectations for marketing its products independently in the U.S., and its expectations regarding how long its current financial resources will last, are forward-looking statements subject to risks and uncertainties. Please see the risks outlined under "Item 1A Risk Factors" of Avigen's Annual Report on Form 10-K for the fiscal year ended December 31, 2005, which is included as part of this Annual Report, for factors that could cause these forward-looking statements not to come true.*

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-K**

**FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934**

For the fiscal year ended December 31, 2005  
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-28272

**AVIGEN, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**1301 Harbor Bay Parkway  
Alameda, California 94502**  
(Address of principal executive offices and zip code)  
**(510) 748-7150**  
(Registrant's telephone number,  
including area code)

**13-3647113**  
(I.R.S. Employer  
Identification No.)

**Securities registered pursuant to Section 12(b) of the Act:**  
None

**Securities registered pursuant to Section 12(g) of the Act:**  
**Common Stock, \$.001 par value**  
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendments to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the Common Stock held by non-affiliates of the registrant as of June 30, 2005, was approximately \$62,074,000 based upon the closing sale price of the registrant's Common Stock as reported on the NASDAQ National Market on such date. Shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates of the registrant. Shares held by all other stockholders have not been excluded, as no other stockholder holds a percentage of the registrant's outstanding Common Stock that the registrant believes is necessary to exercise control over the registrant, nor has any other stockholder otherwise exhibited any ability to exercise control over the registrant.

The number of outstanding shares of the registrant's Common Stock as of March 1, 2006, was 20,910,655 shares.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement for the 2006 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III, Items 10-14 of this Form 10-K.

# ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2005

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## CAUTIONARY INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based upon current expectations that involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements include, but are not limited to:

- the potential of our product development programs, including AV650 for neuromuscular spasm and spasticity, AV411 for neuropathic pain, and AV513 for the treatment of multiple bleeding disorders, including hemophilia;
- our expectations with respect to the clinical development of our product candidates, our clinical trials and the regulatory approval process, including the potential acceleration of clinical development in the U.S. of our two lead product development programs that are based on compounds with prior experience in human clinical trials outside the U.S.;
- our intention to submit Investigational New Drug filings (INDs) to the FDA regarding AV650 and AV411;
- our expectations relating to our selection of additional disease targets for compounds we are developing;
- our expectations with regard to our ability to expand our drug development portfolio through a combination of internal research, acquisitions, and in-licensing opportunities from third parties;
- our expectations regarding our receipt of future revenues based on the development success by Genzyme Corporation in developing and commercializing gene therapy products based on rights included in our assignment agreement;
- our expectations regarding expense savings and cash burn rate resulting from the reduction in our staff level, consolidation of operations, and the sublease of portions of our facilities; and
- our expectations regarding our capital requirements, how long our current financial resources will last, and our needs for additional financing.

We have identified the forward-looking statements we make by using such terms as “may,” “might,” “can,” “will,” “should,” “could,” “would,” “expect,” “plan,” “seek,” “anticipate,” “believe,” “estimate,” “project,” “intend,” “predict,” “potential,” “if” and similar expressions which imply that the statements relate to future events or expectations. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks and uncertainties in greater detail in “Item 1A Risk Factors,” below. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this Form 10-K.

You should read this Form 10-K and the documents that we incorporate by reference completely and with the understanding that our actual future results may be materially different from what we currently expect. We may not update these forward-looking statements, even though our situation may change in the future. We qualify all of our forward-looking statements by these cautionary statements.

## PART I

### Item 1. *Business*

#### Overview

Avigen is a biopharmaceutical company with a mission to develop and commercialize small molecule therapeutics and biologics to treat serious neurological and neuromuscular disorders. Currently, our lead product candidates (AV650 and AV411) primarily address neuromuscular spasm and spasticity and neuropathic pain. Avigen has retained rights to commercialize our products in North America and therefore we expect, when appropriate, to build a sales and marketing infrastructure. We will seek to out-license rights to develop and market our products outside the United States. Over the next year, we do not expect to add products to our development portfolio; however, we will continue to opportunistically look for promising drug candidates to expand our pipeline of compounds in the future through a number of sources, including internal research, acquisitions, and in-licensing. Avigen, Inc. is a Delaware corporation that was incorporated on October 22, 1992 and is based in the San Francisco Bay Area.

In building our pipeline, we focus on selecting compounds we believe have the potential to strongly differentiate themselves from existing therapies and address needs currently unmet by, or with an improved risk-benefit profile when compared to, alternative available treatments. In particular, we believe our drug candidates have unique mechanisms of action in the indications being pursued and have the potential to minimize side-effects such as sedation, that can interfere markedly with resumption of normal activity. Moreover, our two leading programs involve compounds that have been commercialized as human drugs in markets outside the United States. We believe this significant human experience in markets outside the U.S. will help accelerate our clinical development and approval for these product candidates in North America.

We currently have in development AV650, a compound for neuromuscular spasm and spasticity, AV411, a compound for neuropathic pain, and AV513, a compound for the treatment of multiple bleeding disorders, including hemophilia. We also have other candidates in research, including AV333 for neuropathic pain. We have supported the financial needs of our research and development activities since our inception primarily through public offerings and private placements of our equity securities. We expect that we will need to obtain additional funding to support the anticipated future needs of our research and development activities, including the costs to complete clinical trials, as well as to build an appropriate level of sales and marketing infrastructure at the appropriate time if we determine to do so. At December 31, 2005 we had an accumulated deficit of \$171.3 million and cash, cash equivalents, available-for-sale securities, and restricted investments of approximately \$70.4 million. We believe that our capital resources at December 31, 2005, after considering our anticipated spending on our current programs, will be adequate to fund our operating needs for approximately the next three years.

Prior to 2003, Avigen focused exclusively on building a product development portfolio of DNA-based drug delivery technologies, based primarily on adeno-associated virus (AAV) vectors we developed. Our efforts included significant investment in early stage research in the field of gene therapy, which led to our filing of three separate INDs and our initiation of three corresponding phase I or phase I/II clinical trials. In 2003, we began to pursue the development of non-gene therapy products to diversify our portfolio, which is now our focus. In December 2005, we entered into an agreement with Genzyme Corporation, which is intended to provide independent funding for the ongoing development of our gene therapy technologies. Under the terms of the agreement, we assigned to Genzyme our rights to certain AAV-related intellectual property, our gene therapy clinical trial programs for Parkinson's disease and hemophilia, AAV-related contracts, and the use of previously manufactured clinical-grade vector materials. However, if Genzyme fails to diligently pursue the commercialization or marketing of products using the assigned technologies, as specified in the agreement, certain of the rights we assigned could revert back to Avigen at a future date. Under the terms of the agreement, Avigen received a \$12.0 million initial payment and could receive significant future milestone sublicensing fees, and royalty payments based on the successful development of products by Genzyme utilizing technologies previously developed by us.

## Recent Business Highlights

- Entered into an agreement with Genzyme Corporation in December 2005, conveying patent rights and other assets related to our previously developed gene therapy technologies in exchange for an initial payment of \$12.0 million, potential future development-based milestones, sublicensing fees and royalty payments, and certain diligence commitments from Genzyme;
- Completed an in-license agreement in January 2006 for North American rights to AV650 for neuromuscular spasm and spasticity with a division of Sanochemia, an Austrian-based pharmaceutical company;
- Reduced operating expenses associated with prior gene therapy activities by reducing staff and subleasing portions of our facilities, and
- Published data from AV513, our drug candidate for hemophilia, which was highlighted by an editorial in the January 2006 edition of "Thrombosis and Haemostasis."

## Products in Development

### *AV650 — Neuromuscular spasm and spasticity*

**Disease.** Disabling muscle spasm is a sudden, violent, painful contraction of muscles which may be caused by muscle injuries in either acute or chronic settings. These muscle injuries, typically due to trauma or overuse, often result in severe pain and limitation of movement for hours to days. Spasticity is more typically associated with serious neurological disorders such as Multiple Sclerosis, stroke, spinal cord injury, and Cerebral Palsy. Spastic limbs become chronically stiff or rigid because muscles fail to relax, lacking normal regulation of contraction because of damage to the nervous system. Both spasticity and sudden, painful muscle spasms can occur as complications of the neurologic disorders mentioned above.

**Unmet Medical Need.** Many of the current medications have limited clinical utility because of central nervous system side effects. Acute spasms are often treated with muscle relaxants such as Skelaxin® and Flexeril®, and other therapies. Spasticity is often treated with such medications as baclofen, diazepam, tizanidine or clonazepam. Physical therapy regimens may include muscle stretching and range of motion exercises to help prevent shrinkage or shortening of muscles and to reduce the severity of symptoms. Surgery may be recommended for tendon release or to sever the nerve-muscle pathway. While muscle relaxants and antispasmodics can make it possible for patients to begin therapeutic exercise and rehabilitation, common central nervous system side effects, especially sedation and interaction with alcohol, can impair the ability of the patient to perform normal daily functions.

The ideal therapy for disabling muscular spasms and for spasticity would provide excellent safety, tolerability and efficacy, a predictable mechanism of action, and minimal or no muscle weakness, sedation or interaction with alcohol. We believe AV650 may represent such a drug.

**AV650.** In January 2006, we acquired exclusive license rights to develop and commercialize proprietary formulations of the compound tolperisone (AV650) for the North American market. We licensed these rights from SDI Diagnostics International LTD, a division of Sanochemia Pharmazeutika AG. For ease of reference, we refer to SDI Diagnostics throughout this document as "Sanochemia". These rights include Sanochemia's relevant patent filings, as well as their clinical data relating to AV650. Sanochemia has also agreed to supply AV650 to us exclusively for the North American market. Under the terms of the agreement, we made an upfront payment of \$3 million and will make additional payments to Sanochemia based on the parties' achievement of clinical and regulatory product development milestones and sales of AV650.

AV650 is based on an orally administered centrally-acting small molecule that is currently marketed by others for the treatment of muscular spasm and spasticity in Europe and Asia. Avigen is developing AV650 for the North American market under a license and supply agreement with Sanochemia. Sanochemia has completed preclinical studies which are expected to be used by Avigen to file a U.S. IND in 2006. Avigen's development program is designed to build on the extensive ex-U.S. safety and efficacy experience with this compound. AV650 is an important potential therapy for disabling neuromuscular spasms and spasticity. Because of AV650's established record of successful use and safety in many international markets, Avigen is seeking to bring this product to the U.S. market to provide a fast-acting muscle relaxant without sedation or alcohol interaction.

Avigen is investigating the use of AV650 in both muscle spasms and spasticity. For treating acute spasms, we believe that as a safe, non-sedating potential drug, AV650 may not only provide pain relief, but may also prevent the changes in pain signaling pathways in the nervous system that can sometimes lead to chronic pain. For treating chronic muscle spasms and spasticity in serious, irreversible neurologic diseases, we believe that the use of AV650 on a long-term basis may offer both treatment and prevention of recurrent, painful muscle spasms, leading to improved function, sleep uninterrupted by pain, and better quality of life overall.

We are currently in the process of preparing a U.S. IND for filing and intend to initiate a clinical trial in the U.S. within the next year.

*Market for Neuromuscular Spasm and Spasticity Treatment.* The United States prescription market for treatments for neuromuscular spasm and spasticity has been estimated to be approximately \$1.6 billion despite being dominated by generic products. Retail sales of Skelaxin, the only product in this category without generic competition, were in excess of \$450 million in 2005. In Germany, a Western European country in which tolperisone is sold as a generic product, sales of tolperisone represent approximately one third of all sales of pharmaceutical treatments for spasm and spasticity despite not being actively promoted in that market.

#### ***AV411 — Neuropathic pain and other neurological disorders***

*Disease.* Neuropathic pain results from nerve injury and can be particularly difficult to treat, and often becomes chronic. Unlike acute pain, which is usually immediate and short-lived and for which the cause can usually be identified and treated, chronic pain, is continuous and often persists beyond the normal time for healing. It can range from mild to severe and can last months or years. The cause of chronic pain is not always known. Although it can be associated with disorders such as cancer, arthritis, diabetes, or various infections, chronic pain may occur in the absence of any known underlying disease or injury.

Neuropathic pain can distort signaling in the spinal cord such that even normal sensation is perceived as painful. In addition, spontaneous pain, exaggerated responses to otherwise mildly painful sensations, and widespread hypersensitivity extending beyond the area of original injury can become disabling. Chronic neuropathic pain affects up to one-third of individuals with diabetes, and is common after nerve damage caused by various cancer treatments, surgical procedures, trauma, accidental or therapeutic amputation, and as a complication of viruses which target the nervous system such as herpes zoster (the cause of shingles) or HIV. Several hereditary conditions also are associated with neuropathic pain. While estimates of prevalence vary, more than 2 million North Americans are believed to be afflicted with neuropathic pain, and often are inadequately treated with available therapies.

*Unmet Medical Need.* Despite a common understanding among researchers in the field of the pathophysiology and molecular biology of the condition, patients with neuropathic pain are under-served. Current medications, including gabapentin, lidocaine, tramadol, antiepileptics, and tricyclic antidepressants, are largely ineffective at treating a large portion of patients with neuropathic pain. With few exceptions, such medications were not initially developed for pain, but rather other diseases such as depression and epilepsy. For many patients the drugs' profiles limit their utility, because of poor efficacy, significant central nervous system side effects, such as sedation, a short duration of action and/or addictive properties. Other patients with severe neuropathic pain may rely on oral or injected opioids such as morphine for pain relief. Unfortunately, these opioid therapies typically require substantial dose increases over time, and patients often must endure side effects including sedation, cognitive impairment, severe constipation, itching and edema. Addiction and the stigma of using narcotics are also major concerns for both patients and treating physicians.

Avigen is developing a drug to treat neuropathic pain that we believe has a good safety profile with limited central nervous system side effects, offers good efficacy by focusing on a new mechanism of action based on leading neuropathic pain research, provides long lasting relief (especially through the night), and is non-addictive.

*AV411.* Our product in development is based on an approved drug that is currently marketed by others outside the U.S. for a non-pain-related illness. AV411 is an orally administered small molecule with good human pharmacokinetic, pharmacodynamic, and safety profiles at the doses used for non-pain related illnesses. Traditionally, the development of treatments for neuropathic pain has focused on drugs that interact directly with neural cells. Based on our collaborative research with Linda Watkins, Ph.D., from the Center for Neuroscience at

the University of Colorado at Boulder, we believe that certain specialized cells in the nervous system known as "glial cells" or "glia", rather than other nervous system cells known as "neurons" or "nerve cells", are important mediators of neurological pain states. Neurons have long been considered the sole cell types responsible for the development and maintenance of neuropathic pain. Glia traditionally have been disregarded as being little more than supporting cells for neurons. However, recent research has demonstrated that glia enhance the release of neurotransmitters that relay pain information to the spinal cord, and, as is even more strikingly, release substances that increase the excitability of pain-responsive neurons in the spinal cord. These substances, called pro-inflammatory cytokines, create and maintain exaggerated or pathological pain responses. Blocking the activation of glia has been shown in preclinical models to reduce pro-inflammatory cytokines and reverse pathological pain.

We believe AV411 has glial-attenuating properties and have pursued and validated its efficacy in animal models of neuropathic pain. We have demonstrated that AV411 provides relief of allodynia, the painful sensation of a normally innocuous stimulus, in clinically-relevant standard rodent models of neuropathic pain, including chemotherapy- and trauma-induced neuropathic pain. AV411 represents an important potential advance towards what we believe may be an ideal pain therapy with its established safety profile at the doses used for non-pain related illnesses, new mechanism of action in this indication, and long-lasting, non-addictive profile. In addition, data from our preclinical studies in various models of neuropathic pain demonstrate that in certain animals, AV411 preserves normal sensation and has minimal side effects.

We are currently in the process of initiating a Phase I/II trial to assess safety, tolerability and preliminary efficacy in neuropathic pain patients in Europe and Australia, and have submitted applications to the appropriate regulatory authorities. We are also in the process of undertaking non-clinical studies that may enable us to file a U.S. IND by the end of 2006.

**Market for Neuropathic Pain Treatment.** According to the International Association for the Study of Pain and other sources, pain accounts for over 70 million office visits per year in the United States. An American Pain Society study in 1999 found that over 50% of individuals with chronic, non-cancer-related pain classify their pain as severe or very severe, and that fewer than half of these feel that their pain is adequately controlled by currently available medication. In 2002, sales of oral opioids, commonly prescribed for chronic pain, were estimated to exceed \$2 billion. In both 2003 and 2004, sales of Gabapentin, which was developed to treat epilepsy, but is also commonly used to treat moderate neuropathic pain, were estimated to exceed \$2.7 billion. We are not able, however, to ascertain what portion of these sales were for the treatment of moderate neuropathic pain.

**Other indications: morphine tolerance and withdrawal.** Morphine and similar synthetic drugs are collectively known as opioids. Two major side effects of opioid use are tolerance and withdrawal. These undesirable side effects of opioids result in the reluctance of physicians to prescribe them, and the reluctance of patients to use them. Tolerance refers to the need of a patient to require ever-increasing doses to achieve relief from pain. Withdrawal refers to the serious effects of ending opioid therapy due to their addictive properties. However, the appropriate use of opioids can be beneficial, since relief from pain contributes significantly to the healing process. Accordingly, the avoidance of the tolerance and withdrawal associated with opioid therapy represents an opportunity to achieve an equally significant but unmet medical need. Avigen has discovered that AV411 may counteract opioid tolerance and withdrawal symptoms by blocking the activation of certain kinds of glial cells in the spinal cord. Together with our collaborators, Drs. Linda Watkins and Mark Hutchinson at the University of Colorado, Avigen has initiated preclinical studies to demonstrate this hypothesis. Initial results have been positive. With continued success these studies may provide guidance for the design of clinical trials to demonstrate these effects in humans.

#### **AV513 — Bleeding disorders, including hemophilia**

**Disease.** Hemophilia is an inherited blood clotting disorder characterized by the reduction or absence of a clotting factor. There are two major forms of hemophilia: hemophilia A, in which patients are deficient in the factor VIII protein and hemophilia B, in which patients are deficient in the factor IX protein. Due to the inability to produce sustained levels of factor VIII or factor IX in the body, patients with hemophilia can experience frequent internal bleeding during the course of normal daily activities. Currently, patients in developed countries with a severe form of the disease inject themselves with factor VIII or factor IX several times a week in order to prevent these bleeding episodes.

*Unmet Medical Need.* Over the last 25 years, researchers have focused on methods of raising the levels of circulating factor VIII and IX proteins in the body in order to stimulate a normal blood clotting response in patients with hemophilia. As a result, the primary treatment for patients with bleeding disorders includes replacement injections of factor proteins. This approach can be effective, but has significant limitations, primarily related to the inconvenience of intravenous injections. There are no current therapies using orally delivered medications.

*AV513.* We believe AV513 represents a unique asset for Avigen. While outside our strategic focus on neurological and neuromuscular disorders, AV513 leverages our extensive experience with hemophilia. Through our research in large and small animal models of hemophilia with clinically relevant endpoints, we have identified that low doses of certain charged polysaccharides, known to be relatively safe in animals, can stimulate coagulation, offsetting the type of poorly controlled bleeding characteristic of hemophilia. AV513 is one variation of this kind of compound. Based on our research, we believe that AV513 has the potential to become the first non-gene therapy and non-Factor approach to treating hemophilia A and B, and other bleeding disorders such as Factor VII deficiency and severe von Willebrand's disease. Importantly, if AV513 does become an approved therapy, it would become the first therapy for hemophilia to be delivered orally based on approved treatments today. Our strategy is to establish safety and proof-of-concept with the compound through early-stage human clinical trials and to pursue a possible future spin out, sale or out-license.

Data from our research on AV513 were published in the January 2006 edition of "Thrombosis and Haemostasis" and highlighted by an editorial in the same journal. Portions of this publication are available on our website. No part of our website, however, is incorporated into this Annual Report on Form 10-K, including the portions of that publication on our website.

*Market for Hemophilia Treatment.* According to data published by the National Hemophilia Foundation, hemophilia B affects approximately one in every 30,000 males and hemophilia A affects approximately one in every 10,000 males worldwide. Based on these estimates, hemophilia A and B combine to afflict an estimated 50,000 to 65,000 individuals in developed countries, with approximately 40% to 50% of those affected with a severe form of the disease. According to these data, the average annual amount spent by patients for currently-available factor protein exceeds \$100,000 per year. In addition, because protein therapy is often ineffective in preventing muscle, bone, or joint damage requiring surgery, patients may also require an additional \$100,000 to \$150,000 in indirect medical care whenever surgery is needed. We believe that the current market for providing recombinant protein factor VIII and IX to patients in developed countries, who have a severe form of the disease, exceeds \$2.4 billion per year.

#### **Gene Therapy Product Development Interests**

In connection with our agreement with Genzyme Corporation, we do not have any advisory or operational obligations to support the on-going development of gene therapy products. However, under the terms of the agreement, we retain an opportunity to receive significant additional revenues in connection with the potential successful development by Genzyme of gene therapy products based on technologies we originally developed. The additional revenues could be from milestone payments, sublicense fees and/or royalties. Because the transaction is based on our gene therapy intellectual property, the estimate that the potential for us to realize additional revenues under this agreement could extend through approximately 2020, depending on when the last of the issued patents subject to the agreement is scheduled to expire. If Genzyme fails to diligently pursue the commercialization or marketing of products using the assigned technologies, as specified in the agreement, certain rights assigned to Genzyme under the agreement could revert back to Avigen at a future date.

#### **Research Programs**

##### ***Neuropathic Pain***

We maintain a small ongoing preclinical research effort to identify additional opportunities to expand our product development pipeline. Our efforts primarily focus on additional treatments for neuropathic pain and include, through external contract laboratories, a medicinal chemistry optimization effort focused on identification of new chemical entities (NCEs) with glia-attenuating characteristics similar to those of AV411, but with improved physicochemical properties. Additional therapeutic indications for AV411 are also being pharmacologically tested.

We also continue to investigate, through our collaborators, potential products based on the potent anti-inflammatory cytokine interleukin-10 (IL-10) and related molecules. This research, which is also based on glial cell activation, includes our development candidate AV333. AV333 is a plasmid, or DNA sequence, that drives the production of IL-10 within the spinal cord to reverse, we believe, the neuropathic pain resulting from glial activation. AV333 is delivered by an intrathecal injection similar to the routine procedure used to deliver spinal analgesics. Standardized animal models have shown that AV333 is well-tolerated and completely reverses neuropathic pain symptoms for up to ninety days from a single course of treatment. This information was presented at the 8<sup>th</sup> International Conference on Mechanisms and Treatment of Neuropathic Pain in 2005.

#### *Research and Development Expenses*

We incurred research and development expenses of approximately \$13.8 million, \$19.3 million, and \$21.8 million in 2005, 2004, and 2003, respectively. During these years, we did not receive any reimbursements from governmental or other research grants or any other third parties to offset our expenses. As of December 31, 2005, we were party to one collaborative agreement with the University of Colorado, under which we have the potential to receive partial reimbursement for certain research and development expenses under a grant by the National Institutes of Health. We do not expect future reimbursements under this agreement to have a material impact on our financial statements.

#### **Strategic Relationships and Manufacturing**

Research and commercial collaborations will continue to play a significant role in our business strategy. We have built strategic relationships with recognized scientists, clinicians and opinion leaders in the fields that our product candidates address. We feel these relationships, including our relationship with the University of Colorado, enhance the potential of our portfolio of products by providing us with additional resources with the capacity to accelerate a broader array of research testing and by advising us on the latest scientific advances relevant to our needs. We have also established a commercial collaboration with Sanochemia. Under the terms of this collaboration, we have acquired North American development and marketing rights to AV650 and have access to data from Sanochemia's non-U.S. research studies that we believe may help accelerate the pace of our clinical development in the U.S.

We also expect to rely on strategic relationships with third-party manufacturers of the compounds used for our product candidates. We believe that third-party suppliers, such as Sanochemia for AV650, can manufacture high quality drug substance and final drug products in a cost effective manner for use both in our clinical trials and for commercial sale. We believe these third-party suppliers are compliant with the FDA's current good manufacturing practice regulations.

In our AAV transaction with Genzyme Corporation, we sought a company that we believed had the resources and commitment to continue the development of products using AAV-based technologies. Through this transaction, we retained the potential for significant future financial participation in the success of AAV products through contingent development milestones, sublicensing fees and royalty payments. In addition, we delivered on management's commitment to enable work based on AAV technologies we developed to continue for the benefit of patients suffering from Parkinson's disease and hemophilia.

As we continue to identify new development opportunities for compounds in our product candidate portfolio or acquire access to new product candidates, we will continue to evaluate opportunities to increase the potential success of these investments through strategic relationships. These may take the form of additional research and development or manufacturing and supply agreements. We may also seek to license out development and marketing rights to our existing products outside the U.S. If we acquire access to new products or identify new development opportunities for our compounds, including through strategic relationships, we may fund such transactions with the issuance of additional equity securities, which may further dilute our existing stockholders.

#### **Competition**

Pharmaceutical drug development is characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including major pharmaceutical companies and specialized biotechnology companies, engage in activities similar to our activities. Many of the companies we compete with have substantially greater

financial and other resources and larger research and development and clinical and regulatory affairs staffs. We expect our products, if approved, will face competition from both branded pharmaceuticals and generic compounds. In addition, colleges, universities, governmental agencies and other public and private research organizations continue to conduct research and are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technologies that they have developed. We also must compete with these institutions in recruiting highly qualified scientific personnel. Some of our competitors' products and technologies are in direct competition with ours. In addition, we are aware that physicians may utilize other products in an off-label manner for the treatment of disorders we attempt to target.

*Neuromuscular Spasm and Spasticity.* Therapies for acute and chronic spasm and spasticity include Skelaxin (metaxalone, King Pharmaceuticals), Flexeril (cyclobenzaprine, McNeil Consumer & Specialty Pharmaceuticals), Zanaflex (tizanidine, Acorda Therapeutics), Lioresal (baclofen, Novartis), and Soma (carisoprolol, Wallace Laboratories). We anticipate that our products will compete with all of these products. Controlled release formulations or other delivery or dosage forms of these products may be in development and generic versions of many of them are also available. Although we are not aware of any other products in development for neuromuscular spasm or spasticity, products including Sativex (GW Pharmaceuticals) are in development or marketed for indications including the pain associated with spasm and/or spasticity.

*Neuropathic Pain.* Therapies for chronic pain range from over-the-counter compounds, such as aspirin, to opioids, such as morphine. We anticipate that our products will compete with other drugs that are currently prescribed by physicians, including anti-epileptics such as Neurontin (gabapentin, Pfizer), Lyrica (pregabalin, Pfizer), and antidepressants, including Cymbalta, (duloxetine, Eli Lilly & Co). We are aware of additional compounds for chronic neuropathic pain that are currently in development at numerous companies including Bayer, GlaxoSmithKline, Merck & Co., Inc., Novartis AG, Pfizer, Cognetix, Inc., GW Pharmaceuticals plc, Indevus Pharmaceuticals, Inc., Natestch Pharmaceutical Company Inc., Renovis, Inc., Avanir Pharmaceuticals, and Pain Therapeutics, Inc.

Companies that complete clinical trials, obtain required regulatory approvals, and commence commercial sales of their products before their competitors may achieve a significant competitive advantage. In order to compete successfully, we must develop proprietary or otherwise protected positions in products for therapeutic markets that have not been satisfactorily addressed by current alternatives. These products, even if successfully tested and developed, may not be adopted by physicians over other products and may not offer economically feasible alternatives to other therapies.

#### **Marketing and Sales**

We have retained rights to commercialize our current portfolio of products in North America and expect to build marketing and sales capabilities using our own resources. However, we currently do not have a marketing or sales staff. If we are successful in achieving FDA approval of any of our product candidates, we will need to build a commercial capability. There is no assurance that we will be able to build our own commercial organization with our current resources.

#### **Patents and Intellectual Property**

Patents and other proprietary rights are important to our business. We seek to procure patent protection for our anticipated products, or obtain protection from the relevant patents owned by our licensors. Our intellectual property strategy is to file patent applications that protect our technology, inventions and improvements to our inventions that we consider commercially important to the development of our business. We also rely on a combination of trade secrets, know-how and licensing opportunities to develop and protect intellectual property rights pertaining to our products and technology.

As of March 1, 2006, we owned, co-owned, or held licenses to 1 issued U.S. patent and 12 pending U.S. patent applications, as well as corresponding pending non-U.S. patent applications. These patent applications are primarily related to our development portfolio of small molecule-based products and are currently directed to methods of treating various indications using AV411 and formulations of AV650. If issued, all patents within our current portfolio are scheduled to expire in the U.S. between 2019 and 2026.

Some of the compounds used in our development products have been previously patented by others. When we identify previously patented technologies that we believe are critical to the development and commercialization of our products, we seek to in-license such rights under the most favorable terms. Such licenses normally last for the life of the underlying patent. Licenses typically require us to pay license fees and royalties based on the net sales of products that fall within the scope of the license. Some licenses require us to exercise our best efforts or another level of efforts to achieve research, clinical, and commercial milestones and may require us to make additional payments upon the completion of such milestones. Our failure to be diligent or achieve any required development milestones or to negotiate appropriate extensions of any of our license agreements or to make all required milestone and royalty payments when due, and the subsequent decision of any such institution to terminate such license, could have a material adverse effect on our financial position.

The exclusive licenses that we feel are important to our future commercial interests in our development products are:

*Sanochemia.* In January 2006, we entered into an agreement with Sanochemia for rights to develop and market AV650 in North America. We paid an initial license fee of \$3.0 million and will make additional milestone and royalty payments based on the success of the parties' development and commercialization of AV650. Additionally, we must pay to purchase the supply of AV650 formulations from Sanochemia. The license is exclusive for the duration of the patents and pending patent applications that may issue. Under the agreement, we must be diligent in our development of one and under certain circumstances up to two formulations of AV650 and Sanochemia must supply us exclusively with AV650 formulations for North America.

*University of Colorado.* In November, 2003, we entered into an agreement with the University of Colorado for rights to certain intellectual property related to the treatment of chronic pain. The license is exclusive for the duration of any issued patents embodying the licensed intellectual property, or until approximately 2023.

We cannot assure you that the claims in our pending patent applications will be issued as patents, that any issued patents will provide us with significant competitive advantages, or that the validity or enforceability of any of our patents will not be challenged or, if instituted, that these challenges will not be successful. The cost of litigation to uphold the validity and prevent infringement of our patents could be substantial. Furthermore, we cannot assure you that others will not independently develop similar technologies or duplicate our technologies or design around the patented aspects of our technologies. We can provide no assurance that our proposed technologies will not infringe patents or rights owned by others, the licenses to which might not be available to us.

In addition, if we pursue patent applications in foreign countries, their approval processes for patent applications may differ significantly from the processes in the U.S. The patent authorities in each country administer that country's laws and regulations relating to patents independently of the laws and regulations of any other country and the patents must be sought and obtained separately. Therefore, issuance in one country does not necessarily indicate that it can be obtained in other countries. Our policy is to make a case-by-case determination as to whether to file a foreign application to correspond to each of our U.S. applications. Sometimes we decide not to do so. We make the decision with respect to each patent application on a country-by-country basis.

#### ***Gene Therapy-Related Patents***

In December 2005, we transferred the intellectual property rights (including in-licenses) for our AAV gene therapy-based products to Genzyme Corporation. Under the terms of the agreement, we assigned to Genzyme our rights to certain AAV-related intellectual property, our gene therapy clinical trial programs for Parkinson's disease and hemophilia, certain AAV-related contracts, and the use of previously manufactured clinical-grade vector materials. These intellectual property rights included 62 U.S. and international patents owned by us. However, if Genzyme fails to diligently pursue the commercialization and marketing of products using the assigned technology, as specified in the agreement, certain of the rights we assigned could revert back to Avigen at a future date. Under the terms of the agreement, Avigen received a \$12.0 million initial payment and could receive significant future milestone, sublicensing fees and royalty payments based on the successful development of products by Genzyme utilizing technologies previously developed by us.

## **Government Regulation**

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries regulate extensively the clinical development, manufacture, distribution and sale of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval and promotion of our development products. All of our products will require regulatory approval before commercialization. In particular, therapeutic products for human use are subject to rigorous preclinical and clinical testing and other requirements of the Federal Food, Drug, and Cosmetic Act, implemented by the FDA, as well as similar statutory and regulatory requirements of foreign countries and supervisory review boards affiliated with institutions that may perform our clinical trials.

Obtaining marketing approvals and subsequently complying with ongoing statutory and regulatory requirements is costly and time consuming. Any failure by us or our collaborators, third-party manufacturers, licensors or licensees to obtain, or any delay in obtaining regulatory approval or in complying with other requirements, could adversely affect the commercialization of products then being developed by us and our ability to receive product or royalty revenues.

This process of clinically testing drugs and seeking approval to market them can take a number of years and typically requires substantial financial resources. The results of preclinical studies and initial clinical trials are not necessarily predictive of the results from large-scale clinical trials. All clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including the difficulty in obtaining enough subjects, clinical investigators, drug supply, or financial support, or because of unforeseen adverse effects. In addition, as a condition of approval, the FDA also can require further testing of the product and monitoring of the effect of commercialized products, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Upon approval, a drug product may be marketed only in those dosage forms and for those indications for which it is approved.

In addition to obtaining FDA approval for each indication to be treated with each product, each domestic drug product manufacturing establishment must register with the FDA, list its drug products with the FDA, comply with current Good Manufacturing Practices and pass inspections by the FDA. Manufacturers of biological products also must comply with FDA general biological product standards. Moreover, the submission of applications for marketing approval from the FDA may require additional time to complete manufacturing stability studies. Foreign establishments manufacturing drug products for distribution in the United States also must list their products with the FDA and comply with current Good Manufacturing Practices. They also are subject to periodic inspection by the FDA or by local authorities under agreement with the FDA. If we rely on strategic relationships with third-party manufacturers, with either U.S. or foreign manufacturing establishments, as with Sanochemia, we may not be able to ensure effective compliance with these FDA requirements, which could impact the timing and potential success of our development and commercialization of our potential products. Because our current facilities are located in California, if we decide to manufacture any of our products in our facilities that are administered to humans, including products used for testing in clinical trials, we would also be required to obtain a drug manufacturing license from the State of California.

### *Other Regulations*

In addition to regulations enforced by the FDA, in the U.S. we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other federal, state and local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials, and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, we could be held liable for any damages that result from accidental contamination or injury and this liability could exceed our resources. In addition, our handling, care, and use of laboratory rodents are subject to the Guide for the Care and Use of laboratory Animals published by the National Institutes of Health.

Our clinical trials may also involve subjects who reside outside of the U.S. which can involve subsequent monitoring of the subjects' responses at clinical sites outside the U.S. where other regulations apply.

#### **Employees**

As of March 1, 2006, Avigen had 32 full-time employees, including 7 with Ph.D. degrees and 2 with M.D. degrees. Approximately 18 employees are involved in our research and development activities, including research, preclinical development, clinical and regulatory affairs, and quality assurance and quality control, and 14 employees are involved in general administration, finance, legal, and business development activities. We also rely on a number of temporary staff positions and third-party consultants to supplement our workforce. None of our employees are represented by a collective bargaining agreement nor have we ever experienced a work stoppage. We believe that our relationship with our employees is good.

#### **Revenues**

Our revenues in 2005, 2004 and 2003 were \$12,026,000, \$2,195,000 and \$463,000, respectively. Of these amounts, \$12 million in 2005 was from the initial payment received from Genzyme Corporation in December 2005 in connection with our transfer to them of certain AAV gene therapy assets. Also, \$2,125,000 and \$375,000 in 2004 and 2003, respectively, were from the \$2.5 million payment received from Bayer Corporation in 2003 in connection with our development collaboration on a gene therapy-based treatment for hemophilia. We terminated this agreement in December 2004. Both of these corporations are located in the United States. All of our revenues were from companies located in the United States, and all of our long-lived assets are located in the United States.

#### **Available Information and Website Address**

Our website address is [www.avigen.com](http://www.avigen.com); however, information found on our website is not incorporated by reference into this Annual Report on Form 10-K. We file electronically with the Securities and Exchange Commission our annual reports on Form 10-K, quarterly interim reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on or through our website, free of charge, copies of these reports as soon as reasonably practicable after we electronically file or furnish it to the SEC. You can also request copies of such documents by contacting our Investor Relations Department at (510) 748-7150 or sending an email to [ir@avigen.com](mailto:ir@avigen.com).

#### **Item 1A. Risk Factors**

This section briefly discusses certain risks that should be considered by stockholders and prospective investors in Avigen. Many of these risks are discussed in other contexts in other sections of this report.

#### **Risks Related to Our Business**

##### **We expect to continue to operate at a loss and we may never achieve profitability**

Since our inception in 1992, we have not been profitable, and we cannot be certain that we will ever achieve or sustain profitability. To date, we have been engaged in research and development activities and have not generated any revenues from product sales. As of December 31, 2005, we had an accumulated deficit of \$171.3 million. Developing new compounds will require significant additional research and development activities, including preclinical testing and clinical trials, and regulatory approval. We expect these activities, together with our general and administrative expenses, to result in operating losses for the foreseeable future. Our ability to achieve profitability will depend, in part, on our ability to successfully identify, acquire and complete development of proposed products, and to obtain required regulatory approvals and manufacture and market our approved products directly or through business partners.

**If we are able to enhance our existing pipeline of product candidates through the in-license or other acquisition of additional development candidates, we may expose ourselves to new risks that were not identified prior to negotiating the in-license or other acquisition agreement that may prevent us from successfully developing or commercializing our product candidates**

Even if we are able to in-license or acquire potential products, we may fail to identify risks during our due diligence efforts, or new risks may arise later in the development process of our product candidates, that we may be unable to adequately address. If we are unable to address such previously unidentified risks in a timely manner, we will have paid too much for the acquisition or in-license of the potential product, and our business and results of operations will be harmed.

**Our historic research and development activities have primarily focused on our gene delivery products, which raises uncertainty about our ability to develop and commercialize more conventional small molecule product candidates effectively**

We have limited experience in developing or commercializing conventional small molecule product candidates. If we are unable to effectively develop any of the products in our development portfolio or any new products we in-license or acquire, it would significantly reduce our ability to create commercial opportunities for such products.

**Many potential competitors who have greater resources and experience than we do may develop products and technologies that make ours non-competitive or obsolete**

There are many entities, both public and private, including well-known, large pharmaceutical companies, chemical companies, biotechnology companies and research institutions engaged in developing pharmaceuticals for neurological and other applications similar to those that may be targeted by us. Competitors may succeed in developing products that are more effective and less costly than any that we develop and also may prove to be more successful in the manufacturing and marketing of products, which would render the products that we develop non-competitive or obsolete. Furthermore, many of our competitors are more experienced than we are in drug development and commercialization, obtaining regulatory approvals, and product manufacturing and marketing. Accordingly, our competitors may succeed in obtaining regulatory approval for products more rapidly and more effectively than we do. Any product that we successfully develop and for which we gain regulatory approval must then compete for market acceptance and market share. Accordingly important competitive factors, in addition to completion of clinical testing and the receipt of regulatory approval, will include product efficacy, safety, timing and scope of regulatory approvals, availability of supply, marketing and sales capacity, reimbursement coverage, pricing and patent protection.

We are aware that other companies are conducting preclinical studies and clinical trials for products that could compete with products we intend to acquire or develop. See "Item 1. Business — Competition" for a more detailed discussion of the competition we face.

**The regulatory process is expensive, time consuming and uncertain and may prevent us from obtaining required approvals for the commercialization of our product candidates**

Prior to marketing in the United States, any product developed by us must undergo rigorous preclinical testing and clinical trials as well as an extensive regulatory approval process implemented by the FDA. This process is lengthy, complex and expensive, and approval is never certain. Positive results from preclinical studies and early clinical trials do not ensure that positive results will be demonstrated in clinical trials designed to permit application for regulatory approval.

Potential problems we may encounter in the implementation stages of our studies include the chance that we may not be able to conduct clinical trials at preferred sites, obtain sufficient test subjects, or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, the FDA may temporarily suspend clinical trials at any time if it believes the subjects participating in trials are being exposed to unacceptable health risks, if it finds deficiencies in the clinical trial process or conduct of the investigation, or to better analyze data surrounding any unexpected developments.

Because of the risks and uncertainties in biopharmaceutical development, our products could take a significantly longer time to gain regulatory approval than we expect or may never gain FDA approval. If we do not receive these necessary approvals from the FDA, we will not be able to generate substantial revenues or become profitable.

**We may not be successful in obtaining required foreign regulatory approvals, which would prevent us from marketing our products internationally**

We cannot be certain that we will obtain any regulatory approvals in other countries. In order to market our products outside of the United States, we must comply with numerous and varying foreign regulatory requirements implemented by foreign regulatory authorities. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. Foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the regulatory authorities of any other country.

**If we fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, our products could be subject to restrictions or withdrawal from the market**

Any product for which we obtain marketing approval from the FDA, along with the manufacturing processes, post-approval clinical data collection and promotional activities for such product, will be subject to continual review and periodic inspection by the FDA and other regulatory bodies. After approval of a product, we will have significant ongoing regulatory compliance obligations. Later discovery of previously unknown problems with our products or manufacturing processes, or failure to comply with regulatory requirements, may result in penalties or other actions, including removal of a product or products from the market.

**We may need to secure additional financing to acquire and complete the development and commercialization of our products**

At December 31, 2005 we had cash, cash equivalents, available-for-sale securities, and restricted investments of approximately \$70.4 million. We anticipate that our existing capital resources as of December 31, 2005 will be adequate to fund our needs for approximately three years. However, beyond that, or earlier if we are successful in pursuing additional indications for compounds in our portfolio or acquiring additional product candidates, we may require additional funding to complete the research and development activities currently contemplated, to acquire new products, and to commercialize our products. Our future capital requirements will depend on many factors, including:

- continued scientific progress in research and development programs;
- the scope and results of preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing, prosecuting and enforcing patent claims and other intellectual property rights;
- the costs involved in obtaining licenses to patented technologies from third parties that may be needed to commercialize our products;
- how successful, if at all, we are at expanding our drug development portfolio through a combination of internal research, acquisitions, and in-licensing compounds, and the nature of the consideration we pay for acquiring or in-licensing compounds;
- competing technological developments;
- the cost of manufacturing for clinical trials and commercialization;
- the cost of commercialization activities; and
- other factors which may not be within our control.

We intend to continue to seek additional funding through public or private equity or debt financing, when market conditions allow, or through additional collaborative arrangements with corporate partners. If we raise

additional funds by issuing equity securities there may be further dilution to existing stockholders. We cannot assure our investors that we will be able to enter into such financing arrangements on acceptable terms or at all. Without such additional funding, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs.

**We expect to depend on third parties to manufacture compounds for our product candidates. If these manufacturers fail to meet our requirements and the requirements of regulatory authorities, our business, financial condition and results of operations could be harmed**

We intend to use third parties to manufacture active pharmaceutical ingredients and supplies for our product candidates. For example, we rely entirely on Sanochemia to manufacture and supply to us AV650 for both clinical and commercial supply. We have entered into an exclusive arrangement with them for this. We have no experience in manufacturing small molecule compounds and do not have any manufacturing facilities. If we are unable to enter into supply and processing contracts with third party manufacturers or processors for our other product candidates, or even if we are able to enter into supply and processing contracts, if Sanochemia or such other manufacturers or processors are unable to or do not satisfy our requirements, or if disputes arise between us and our suppliers, we may experience a supply interruption and we may incur additional cost and delay in the clinical development or commercialization of our products. If we are required to find an additional or alternative source of supply, there may be additional cost and delay in the development or commercialization of our products. Furthermore, with AV650, while we are entitled to require Sanochemia to redundantly source certain AV650 finishing activities beginning as of the time and solely to the extent specified in the contract, we are not entitled to establish a second or independent source of AV650 supply other than under specified circumstances. In this and any future exclusive supply contracts for our full requirements, we are or will be particularly reliant on our suppliers. Additionally, the FDA inspects all commercial manufacturing facilities before approving a New Drug Application for a drug manufactured at those sites. If any of our manufacturers or processors fails to pass the FDA inspection, our clinical trials, the potential approval and eventual commercialization of our products may be delayed.

**If we are able to bring our potential products to market, we will face a number of risks outside of our control as we may be dependent on others to market our products, as well as to facilitate demand for our products**

Even if we are able to develop our potential products and obtain necessary regulatory approvals, we have no experience in marketing or selling any of our proposed products. We currently do not have a marketing or sales staff. If we are successful in achieving FDA approval of any product candidate, including any product that we may acquire as a result of our business development efforts, we will need to build a commercial capability. The development of a marketing and sales capability will require significant expenditures, management resources and time. We may be unable to build such a sales force, the cost of establishing such a sales force may exceed any product revenues, or our marketing and sales efforts may be unsuccessful. We may not be able to find a suitable sales and marketing partner for our products. If we are unable to successfully establish a sales and marketing capability in a timely manner or find suitable sales and marketing partners, our business and results of operations will be harmed. Even if we are able to develop a sales force or find a suitable marketing partner, we may not successfully penetrate the markets for any of our proposed products.

We intend to enter into distribution and marketing agreements with other companies for our products outside the U.S. and do not anticipate establishing our own foreign sales and marketing capabilities for any of our potential products in the foreseeable future. If any of our foreign marketing partners do not perform under future agreements, we would need to identify an alternative marketing and distribution partner, or market this product ourselves, and we may not be able to establish adequate marketing capabilities for this product.

Our success is dependent on acceptance of our products. We cannot assure you that our products will achieve significant market acceptance among patients, physicians or third-party payers, even if we obtain necessary regulatory and reimbursement approvals. Failure to achieve significant market acceptance will harm our business. In addition, we cannot assure you that these products will be considered cost-effective and that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a profitable basis. In both the United States and elsewhere, sales of medical products and treatments are dependent, in part, on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. We cannot predict

whether any legislative or regulatory proposals will be adopted or the effect that such potential proposals or managed care efforts may have on our business.

**We may be unable to attract and retain the qualified employees, consultants and advisors we need to be successful**

We are highly dependent on key members of our senior management and scientific staff. The loss of any of these persons could substantially impair our research and development efforts and impede our ability to develop and commercialize any of our products. Recruiting and retaining qualified scientific, technical and managerial personnel will also be critical to our success. Biotechnology and pharmaceutical personnel with these skills are in high demand. As a result, competition for and retention of personnel, particularly for employees with technical expertise, is intense and the turnover rate for these people can be high.

In addition, we rely on consultants and advisors to assist us in formulating our research and development strategy. A majority of our scientific advisors are engaged by us on a consulting basis and are employed on a full-time basis by others. We have limited control over the activities of these scientific collaborators which often limit their availability to us. Failure of any of these persons to devote sufficient time and resources to our programs could delay our progress and harm our business. In addition, some of these collaborators may have consulting or other advisory arrangements with other entities that may conflict or compete with their obligations to us.

**Changes in board and management composition could adversely disrupt our operations.**

We have recently experienced changes to our board of directors and senior management team, including the death of our Chairman of the Board in December 2005 and the resignation of our Chief Financial Officer in January 2006. We have filled these two roles with members of our current board and executive staff. We are in the process of recruiting additional candidates to fill the vacancy and expand the size of our board of directors, and hope to add to our commercialization and clinical development expertise. These changes could be disruptive, and we may experience difficulties in attracting and retaining new directors or in integrating members of the Board and management team into new roles with respect to our business.

**We face the risk of liability claims which may exceed the scope or amount of our insurance coverage**

The manufacture and sale of medical products entails significant risk of liability claims. We currently carry liability insurance; however, we cannot assure you that this coverage will remain in place or that this coverage will be adequate to protect us from all liabilities which we might incur in connection with the use of our products in clinical trials or the future use or sale of our products upon commercialization. In addition, we may require increased liability coverage as additional products are used in clinical trials and commercialized. This insurance is expensive and may not be available on acceptable terms in the future, if at all. A successful liability claim or series of claims brought against us in excess of our insurance coverage could harm our business. We must indemnify certain of our licensors against any liability claims brought against them arising out of products developed by us under these licenses.

**Our use of hazardous materials exposes us to the risk of environmental liabilities, and we may incur substantial additional costs to comply with environmental laws in connection with the operation of our research and manufacturing facilities**

We use radioactive materials and other hazardous substances in our research and development operations. As a result, we are potentially subject to substantial liabilities related to personal injuries or property damages they may cause. In addition, clean up costs associated with radioactivity or other hazardous substances, and related damages or liabilities could be significant and could harm our business. We do not believe that our current level of use of these controlled substances will require any material capital expenditures for environmental control facilities for the next few years. We are also required to comply with increasingly stringent laws and regulations governing environmental protection and workplace safety which could impose substantial fines and criminal sanctions for violations. If we were to fail to maintain compliance with these laws and regulations we could require substantial additional capital.

**The testing of our potential products relies heavily on the voluntary participation of subjects in our clinical trials, which is not within our control, and could substantially delay or prevent us from completing development of such products**

The development of our potential products is dependent upon collecting sufficient data from human clinical trials to demonstrate safe and effective results. We experienced delays in enrolling subjects in our previous gene therapy clinical trials, and we may experience similar difficulties with our current products in the future. Any delay or failure to recruit sufficient numbers of subjects to satisfy the level of data required to be collected under our clinical trial protocols could prevent us from developing any products we may target.

**AAV Gene therapy technology is new and developing rapidly and Genzyme Corporation may face delays in developing products based on technologies included in our assignment agreement, in which case we may not receive any additional milestone, sublicense or royalty payments in connection with the agreement**

Development of drug products, including gene therapy products, is unpredictable and is subject to many risks and uncertainties. We are not aware of any gene therapy products that Genzyme Corporation has fully developed or for which it has received regulatory approval for commercial sale in the U.S. As such, we face the risk that they will not be able to develop or receive regulatory approval for commercial sale of any product candidates that might utilize technologies included in our assignment agreement. Therefore, we may never receive any additional milestone, sublicense or royalty payments in connection with our previous work on AAV gene therapy activities.

#### **Risks Related to Our Intellectual Property**

**Our success is dependent upon our ability to effectively protect our patents and proprietary rights, which we may not be able to do**

Our success will depend to a significant degree on our ability to obtain patents and licenses to patent rights, preserve trade secrets, and to operate without infringing on the proprietary rights of others. If we are not successful in these endeavors, our business will be substantially impaired.

To date, we have filed a number of patent applications in the U.S. relating to technologies we have developed or co-developed. In addition, we have acquired licenses to certain issued patents and pending patent applications. We cannot guarantee that patents will issue from these applications or that any patent will issue on technology arising from additional research or, if patents do issue, that claims allowed will be sufficient to protect our technologies.

The patent application process takes several years and entails considerable expense. The failure to obtain patent protection on the technologies underlying certain of our proposed products may have a material adverse effect on our competitive position and business prospects. Important legal issues remain to be resolved as to the scope of patent protection for biotechnology and pharmaceutical products, and we expect that administrative proceedings, litigation, or both may be necessary to determine the validity and scope of our and others' patents. These proceedings or litigation may require a significant commitment of our resources in the future.

If patents can be obtained, we cannot assure you that any of these patents will provide us with any competitive advantage. For example, others may independently develop similar technologies or duplicate any technology developed by us, and patents may be invalidated or held unenforceable in litigation. For example, for at least one of our product candidates, the compound in it is no longer patented. For that candidate, we intend to rely (if they issue) primarily on formulation and potentially use patent claims (combined with any available regulatory exclusivity) rather than more traditional composition-of-matter patent claims on the active ingredient itself. Formulation and use coverage may not be effective in preventing others from marketing the active compound in competition with us. As another example, in our AV411 program, the compound is off-patent. We have filed and own a patent application on its use for the indications for which we are developing. However, we cannot assure you that this patent application, even if it one day issues as a patent, will effectively prevent others from marketing the same drug for the indications currently claimed by our patent application.

We also rely on a combination of trade secret and copyright laws, employee and third-party nondisclosure agreements and other protective measures to protect intellectual property rights pertaining to our products and technologies. We cannot be certain that these measures will provide meaningful protection of our trade secrets,

know-how or other proprietary information. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States. We cannot assure you that we will be able to protect our intellectual property successfully.

**We may not be able to patent certain formulations of our products in development and may need to rely on protections under the Hatch-Waxman Act to prevent generics from copying our product candidates**

Certain of our products in development are molecules that are in the public domain. While we are working to obtain patent protection for our formulations, manufacturing processes, and uses of these molecules, there is no guarantee that we will be able to do so. In cases where no patent protection can be obtained, regulatory exclusivity providing protection against generic competition can be obtained under the Hatch-Waxman Act if we are the first to obtain regulatory approval to market these compounds. There is no guarantee that we will be able to do so. Biotechnology or pharmaceutical companies with greater financial and personnel resources may be able to obtain regulatory approval to market one or more of these compounds prior to our obtaining such approval. Failure to obtain patent protection or regulatory exclusivity will adversely impact our ability to commercialize our products and realize a positive return on our investment.

**Other persons may assert rights to our proprietary technology, which could be costly to contest or settle**

Third parties may assert patent or other intellectual property infringement claims against us with respect to our products, technologies, or other matters. Any claims against us, with or without merit, as well as claims initiated by us against third parties, can be time-consuming and expensive to defend or prosecute and resolve. There may be third-party patents and other intellectual property relevant to our products and technology which are not known to us. We have not been accused of infringing any third party's patent rights or other intellectual property, but we cannot assure you that litigation asserting claims will not be initiated, that we would prevail in any litigation, or that we would be able to obtain any necessary licenses on reasonable terms, if at all. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may have to participate in interference proceedings declared by the Patent and Trademark Office to determine priority of invention, which could result in substantial cost to us, even if the outcome is favorable to us. In addition, to the extent outside collaborators apply technological information developed independently by them or by others to our product development programs or apply our technologies to other projects, disputes may arise as to the ownership of proprietary rights to these technologies.

**We may be required to obtain rights to proprietary genes and other technologies to further develop our business, which may not be available or may be costly**

We currently investigate and use certain gene sequences or proteins encoded by those sequences, including the IL-10 gene, and manufacturing processes that are or may become patented by others. As a result, we may be required to obtain licenses to these gene sequences or proteins or other technology in order to test, use or market products. We may not be able to obtain these licenses on terms favorable to us, if at all. In connection with our efforts to obtain rights to these gene sequences or proteins or other technology, we may find it necessary to convey rights to our technology to others. Some of our products may require the use of multiple proprietary technologies. Consequently, we may be required to make cumulative royalty payments to several third parties. These cumulative royalties could become commercially prohibitive. We may not be able to successfully negotiate these royalty adjustments to a cost effective level, if at all.

**If we do not fulfill our obligations under our in-license agreements, including our in-license for AV650, we may not be able to retain our rights under those agreements and may be forced to cease our activities with the affected product candidate or technology**

We have entered into license agreements with third parties for technologies related to our product development programs. Typically, we have obligations under these agreements to diligently pursue commercialization of products using the technologies licensed to us, among other obligations including payment, patent prosecution, information-sharing and licensing obligations. We have these kinds of obligations to Sanochemia under our AV650 agreement with them. If we fail to fulfill our obligations under these agreements and fail to obtain a waiver of any material failure to fulfill such obligations, the licensor may terminate these license agreements with relatively short notice

to us. Termination of any of our license agreements could harm our business and force us to cease our activities with the affected product candidate or technology.

Similarly, if disputes arise between us and our licensors, our rights to the licensed product candidates and technologies could be threatened. In addition, any such dispute could harm us through taking our management's time and attention to resolve the dispute.

### **Risks Related to Our Stock**

#### **Anti-takeover effects of certain charter provisions and Delaware law may negatively affect the ability of a potential buyer to purchase some or all of our stock at an otherwise advantageous price, which may limit the price investors are willing to pay for our common stock**

Certain provisions of our charter and Delaware law may negatively affect the ability of a potential buyer to attempt a takeover of Avigen, which may have a negative effect on the price investors are willing to pay for our common stock. For example, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, and privileges of those shares without any further vote or action by the stockholders. This would enable the Board of Directors to establish a shareholder rights plan, commonly referred to as a "poison pill," which would have the effect of making it more difficult for a third party to acquire a majority of the outstanding voting stock of Avigen. In addition, our board of directors is divided into three classes, and each year on a rotating basis the directors of one class are elected for a three-year term. This provision could have the effect of making it less likely that a third party would attempt to obtain control of Avigen through Board representation. Furthermore, certain other provisions of our restated certificate of incorporation may have the effect of delaying or preventing changes in control or management, which could adversely affect the market price of our common stock. In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, an anti-takeover law.

#### **Our stock price is volatile, and as a result investing in our common stock is very risky**

From January 1, 2004 to March 1, 2006, our stock price has fluctuated between a range of \$2.63 and \$7.93 per share. We believe that various factors may cause the market price of our common stock to continue to fluctuate, perhaps substantially, including announcements of:

- technological innovations or regulatory approvals;
- results of clinical trials;
- new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights;
- achievement or failure to achieve certain developmental milestones;
- public concern as to the safety of pharmaceutical products;
- health care or reimbursement policy changes by governments or insurance companies;
- developments of significant acquisitions or in relationships with corporate partners;
- announcements by us regarding financing transactions and/or future sales of equity securities; or
- changes in financial estimates or securities analysts' recommendations.

In addition, in recent years, the stock market in general, and the shares of biotechnology and health care companies in particular, have experienced extreme price fluctuations. These broad market and industry fluctuations may cause the market price of our common stock to decline dramatically.

**Our future financial results will be affected by changes in the accounting rules governing the recognition of stock-based compensation expense.**

Through December 31, 2005, we measured compensation expense for our employee stock compensation plans under the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25 ("APB No. 25"), "Accounting for Stock Issued to Employees." Beginning January 1, 2006, we are required to measure equity compensation expense using the fair value method, which will adversely affect our results of operations by increasing our reported losses or reducing future reported income and which may adversely affect our stock price. Had we accounted for our compensation expense under the fair value method of accounting prescribed by FAS 123, our equity compensation expenses for 2005, 2004, and 2003 would have been significantly higher, increasing by approximately \$2.2 million, \$6.4 million and \$9.9 million, net of reported amounts prescribed under APB No. 25, respectively.

**Item 1B. Unresolved Staff Comments**

We have no unresolved written comments from the Securities and Exchange Commission.

**Item 2. Properties**

Our headquarters are located in a commercial neighborhood of Alameda, California, and consist of two leased buildings with an aggregate of 112,500 square feet. These buildings include facilities for laboratory research and development, manufacturing and office space. One building, which represents approximately 45,000 square feet, is under a 5-year lease that is scheduled to expire in May 2008. A second adjacent building, which represents approximately 67,500 square feet, is under a 10-year lease that is scheduled to expire in November 2010. The scheduled annual rental expense for 2006 under these leases is approximately \$2.3 million. We currently sublease 15,250 square feet and 11,000 square feet, respectively, from the two buildings to two separate tenants. These subleases run concurrent with the duration of our underlying lease terms. Under these leases, we are scheduled to receive annual sublease rental income in 2006 of approximately \$0.5 million and reimbursement for a portion of the related facilities overhead costs which will be recorded as a reduction to our operating expenses. We believe that the remaining space not under sublease in these two buildings is adequate for our projected needs for the foreseeable future.

**Item 3. Legal Proceedings**

As of March 1, 2006, we were not involved in any legal proceedings.

**Item 4. Submission of Matters to a Vote of Security Holders**

None.

**Executive Officers of the Registrant**

Our executive officers and their respective ages and positions as of March 14, 2006, are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Kenneth G. Chahine, J.D., Ph.D. ...	41	President, Chief Executive Officer and Director
Michael D. Coffee .....	60	Chief Business Officer
Dawn McGuire, M.D. ....	52	Chief Medical Officer
Kirk Johnson, Ph.D. ....	46	Vice President, Preclinical Research
M. Christina Thomson, J.D. ....	35	Vice President, Corporate Counsel and Secretary
Andrew A. Sauter .....	39	Vice President, Finance

All of our officers are elected annually by the Board of Directors. There is no family relationship between or among any of the officers or directors.

*Kenneth G. Chahine, J.D., Ph.D.*, was appointed President, Chief Executive Officer and director of Avigen in March 2004. Dr. Chahine has served as Avigen's Chief Operating Officer since July 2002, and as Vice President, Business Development and Intellectual Property since 1998. Prior to joining Avigen, Dr. Chahine worked at the patent law firm of Madson & Metcalf, P.C. in Salt Lake City, Utah from 1994 to 1998. From 1992 to 1993, he worked as a research scientist at Parke-Davis Pharmaceuticals, a pharmaceutical company, and held another research

scientist post at the University of Utah Department of Human Genetics from 1994 to 1996. Dr. Chahine served as western regional news and legal correspondent for *Nature Biotechnology* from 1996 to 2002. Dr. Chahine holds a J.D. from the University of Utah and a Ph.D. in biochemistry and molecular biology from the University of Michigan.

*Michael D. Coffee* has served as Avigen's Chief Business Officer since February 2005. Prior to joining Avigen, Mr. Coffee co-founded the Alekta Group, LLC in 2004, a consulting firm, to provide a comprehensive range of pharmaceutical development consulting services to emerging pharmaceutical companies. From 2001 to 2004 Mr. Coffee served as President and Chief Operating Officer of Amarin Pharmaceuticals, Inc., the U.S. drug development and marketing subsidiary of Amarin Corporation PLC. Mr. Coffee also served as President and Chief Operating Officer of Elan Pharmaceuticals, North America from 1998 to 2001 and held marketing and executive management positions, including President and Chief Operating Officer, of Athena Neurosciences, Inc. between 1991 and 1998. Mr. Coffee received a BS in biology from Siena College.

*Dawn McGuire, M.D.*, has served as Avigen's Chief Medical Officer since January 2004. Dr. McGuire has provided leadership in both pharmaceutical and biotechnical corporate settings, most recently as Chief Scientific Officer of Eunoe, Inc. (previously CSFluids, Inc.), a medical device company, from 2002 to January 2004. She was President and Chief Executive Officer of CSFluids from 1999 to 2002. From 1999 to 2000, Dr. McGuire also served as Vice President, Medical Affairs Worldwide at Collagen Corporation, a healthcare products company. From 1997 to 1999, Dr. McGuire served as Vice President, Clinical Research and Medical Affairs at Elan Pharmaceuticals and was responsible for, among other programs, the development through FDA submission of ziconotide (Prialt<sup>TM</sup>). Dr. McGuire is a board-certified neurologist and has led clinical development programs in neuropathic pain, Alzheimer's disease, AIDS dementia, Lou Gehrig's disease, Multiple Sclerosis, and stroke. She is the co-author of over 40 scientific articles, book chapters, and invited reviews in neurotherapeutics. Since 2000, Dr. McGuire has served as a Scientific Reviewer and Study Section Member of the National Institute of Neurological Disorders and Stroke. Dr. McGuire received her B.A. with high honors from Princeton University, her M.D. from Columbia University College of Physicians and Surgeons, and trained in neurology at the University of California, San Francisco, followed by an NIH-funded postdoctoral fellowship in clinical trial design and experimental therapeutics.

*Kirk Johnson, Ph.D.*, joined Avigen in January 2004 and was appointed Vice President, Preclinical Development in June 2004. Prior to joining Avigen, Dr. Johnson was Senior Director, Pharmacology & Preclinical Development and a member of the executive management team of Genesoft Pharmaceuticals from 2001 to 2004. From 1991 to 2001, Dr. Johnson was employed in both protein and small molecule therapeutic research and development at Chiron Corporation, a biopharmaceutical company, and eventually served as Director, Pharmacology and Preclinical Research. Dr. Johnson was involved in leading IND-enabling programs, supporting clinical development, and contributing to successful IND and NDA filings at Chiron and Genesoft. In addition to general pharmacology and other preclinical development responsibilities, he has lead research and clinical development projects for diverse indications including neuropathic pain, hemophilia, antibacterials, diabetes, obesity, acute inflammation and cardiovascular disease and has published more than 50 manuscripts and holds 4 U.S. patents. Dr. Johnson earned a B.S. in toxicology from U.C. Davis, and a Ph.D. in pharmacology and toxicology from the Medical College of Virginia. He completed postdoctoral fellowships studying the mechanism of action of IL-2 from 1986-1989 with Dr. Kendall Smith at Dartmouth College and from 1990-1991 with Dr. Marian Koshland at the University of California, Berkeley.

*M. Christina Thomson, J.D.*, joined Avigen in February 2000 and was appointed Vice President, Corporate Counsel in June 2004. She has also served as our Chief Compliance Officer since March 2004 and Corporate Secretary since January 2005. Ms. Thomson is a registered patent attorney, and has managed significant growth in Avigen's patent portfolio over the last five years. Ms. Thomson also oversees the company's litigation and administrative patent proceedings, as well as contract administration. Prior to joining Avigen, Ms. Thomson worked as a patent attorney with the law firm Knobbe Martens Olson & Bear LLP in Newport Beach, California, as a patent agent with Madson & Metcalf, P.C. in Salt Lake City, Utah, and as a scientist for Myriad Genetic Laboratories. Ms. Thomson holds a J.D. from the University of Utah College of Law and an M.S. in biology from the University of Utah.

*Andrew A. Sauter* was appointed Vice President, Finance in January 2006, having joined Avigen as Controller in November 1999. Mr. Sauter is Avigen's principal financial officer. Mr. Sauter oversees the financial reporting obligations of Avigen and has been responsible for Sarbanes-Oxley compliance. From 1992 to 1999, Mr. Sauter worked for BankAmerica Corporation in a variety of positions, including most recently as a vice president in the Capital Markets Finance organization. From 1989 to 1992, he worked for Ernst & Young LLP. Mr. Sauter is a certified public accountant and holds a B.A. degree in economics from Claremont McKenna College.

## PART II

### **Item 5. *Market for Registrants Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities***

Shares of Avigen's common stock commenced trading on the NASDAQ National Market on May 22, 1996, under the symbol "AVGN". As of March 1, 2006, there were approximately 133 holders of record of our common stock.

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future.

The following table sets forth, for fiscal periods indicated, the range of high and low closing sales prices available for the years ended December 31, 2004 and 2005.

<u>Year ended December 31, 2004</u>	<u>High</u>	<u>Low</u>
Quarter End 3/31/04 .....	\$7.93	\$5.29
Quarter End 6/30/04 .....	\$5.40	\$3.00
Quarter End 9/30/04 .....	\$3.79	\$3.12
Quarter End 12/31/04 .....	\$3.77	\$3.15
 <u>Year ended December 31, 2005</u>	 <u>High</u>	 <u>Low</u>
Quarter End 3/31/05 .....	\$3.25	\$2.78
Quarter End 6/30/05 .....	\$3.54	\$2.78
Quarter End 9/30/05 .....	\$3.70	\$2.63
Quarter End 12/31/05 .....	\$3.27	\$2.70

On March 1, 2006, the closing sales price of Avigen common stock was \$5.84 per share.

# **Item 6. Selected Financial Data**

The following tables should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 of this report and the financial statements and related notes included in Item 8 of this report.

Statement of Operations Data: <i>(in thousands, except share and per share amounts)</i>	Year Ended December 31,					(1) Six Months Ended December 31, 2001	Fiscal Year Ended June 30, 2001	Period from October 22, 1992 (inception) through December 31, 2005
	2005	2004	2003	2002	2001			
	(unaudited)							
Revenue .....	\$ 12,026	\$ 2,195	\$ 463	\$ 57	\$ 94	\$ 8	\$ 116	\$ 15,471
Operating expenses:								
Research and development ..	13,775	19,344	21,805	24,809	22,333	11,465	17,041	141,280
General and administrative ...	8,264	8,367	7,399	8,146	7,559	3,957	6,761	60,454
Impairment loss related to long-lived assets .....	6,130	—	—	—	—	—	—	6,130
In-license fees .....	—	—	—	—	—	—	—	5,034
Total operating expenses ...	28,169	27,711	29,204	32,955	29,892	15,422	23,802	212,898
Loss from operations .....	(16,143)	(25,516)	(23,741)	(32,898)	(29,798)	(15,414)	(23,686)	(197,427)
Interest expense .....	(323)	(209)	(250)	(278)	(347)	(204)	(180)	(2,703)
Interest income .....	1,682	1,905	3,282	5,569	9,364	4,316	7,907	28,992
Other income (expense), net ..	88	(103)	(65)	(132)	(68)	(17)	(55)	(137)
Net loss .....	\$ (14,696)	\$ (23,923)	\$ (23,774)	\$ (27,739)	\$ (20,849)	\$ (11,319)	\$ (16,014)	\$ (171,275)
Basic and diluted net loss per common share .....	\$ (0.71)	\$ (1.17)	\$ (1.28)	\$ (1.38)	\$ (1.05)	\$ (0.57)	\$ (0.85)	
Shares used in basic and diluted net loss per common share calculation .....	20,624,229	20,362,155	20,149,214	20,080,998	19,845,640	19,959,941	18,730,437	

## **Balance Sheet Data:**

<i>(in thousands)</i>	December 31,					June 30,
	2005	2004	2003	2002	2001 (1)	2001
Cash, cash equivalents, available-for-sale securities and restricted investments .....	\$ 70,388	\$ 76,218	\$ 98,878	\$ 119,224	\$148,254	\$157,737
Working capital .....	59,649	63,873	86,051	107,398	137,486	151,341
Total assets .....	76,264	90,507	116,595	140,686	168,409	174,946
Long-term obligations .....	9,282	9,064	10,592	8,852	8,558	5,391
Deficit accumulated during development stage .....	(171,275)	(156,579)	(132,656)	(106,882)	(79,143)	(67,823)
Stockholders' equity .....	65,464	79,875	103,886	130,057	157,350	167,182

(1) We changed our fiscal year end from June 30 to December 31, effective December 31, 2001.

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties. Avigen's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, those discussed herein and in "Item 1A — Risk Factors".*

### **Overview**

Avigen is a biopharmaceutical company focused on developing and commercializing small molecule therapeutics and biologics to treat serious neurological and neuromuscular disorders. Our current lead product candidates primarily address neuromuscular spasm and spasticity and neuropathic pain. Our goal is to retain rights to commercialize our products in North America and therefore we expect, when appropriate, to build a sales and marketing infrastructure. We expect that we will seek to out-license rights to develop and market our products outside the United States. We will also continue to look for opportunities to expand our pipeline of compounds through a combination of internal research, acquisitions, and in-licensing as appropriate.

In building our pipeline, we focus on selecting compounds we believe have the potential to strongly differentiate themselves from existing therapies and address needs currently unmet by, or with an improved risk-benefit profile when compared to, alternative available treatments. In particular, we believe our drug candidates have unique mechanisms of action in the indications being pursued and have the potential to minimize side-effects, such as sedation, that can interfere markedly with resumption of normal activity. Moreover, our two leading programs are commercially approved pharmaceuticals outside the United States. We believe this significant human experience in markets outside the U.S. will help accelerate our clinical development and approval for these products in North America.

In January 2006, we acquired exclusive license rights to develop and commercialize proprietary formulations of the compound tolperisone (AV650) for the North American market. These rights include relevant patent filings, as well as clinical data held by Sanochemia relating to AV650. Sanochemia has also agreed to supply AV650 to us exclusively for the North American market. Under the terms of the agreement, we made an upfront payment of \$3 million and will make additional payments to Sanochemia, our European collaborator, based on the parties' achievement of clinical and regulatory product development milestones and sales of AV650.

Prior to 2003, we focused exclusively on building a product development portfolio of DNA-based drug delivery technologies based primarily on AAV vectors we developed. Our efforts included significant investment in early stage research in the field of gene therapy, which led to our filing of three separate INDs and our initiation of three corresponding phase I or phase I/II clinical trials. In 2003, we began to pursue the development of non-gene therapy products to diversify our portfolio, which is now our focus. In December 2005, we entered into an agreement with Genzyme Corporation, which is intended to provide independent funding for the ongoing development of our gene therapy technologies. Under the terms of the agreement, we assigned to Genzyme our rights to certain AAV-related intellectual property, our gene therapy clinical trial programs for Parkinson's disease and hemophilia, AAV-related contracts, and the use of previously manufactured clinical-grade vector materials. However, if Genzyme fails to diligently pursue the commercialization or marketing of products using the assigned technology, as specified in the agreement, certain of the rights we assigned could revert back to Avigen at a future date. Under the terms of the agreement, we received a \$12.0 million initial payment and could receive significant future milestone, sublicensing fees and royalty payments based on the successful development of products by Genzyme utilizing technologies previously developed by us.

From 2000 through 2004, we were party to a collaboration agreement with Bayer Corporation to develop a gene therapy product for hemophilia. In 2003, Bayer paid us \$2.5 million to support our development of the product candidate. That payment was originally recorded as deferred revenue and was scheduled to be recognized ratably as revenue over the estimated five-year development period associated with the product. In May 2004, we suspended the related clinical trial and other development activities, and accelerated the recognition of the remaining portion of deferred revenue. We have terminated the collaboration agreement with Bayer and do not expect to receive any additional payments associated with similar gene therapy activities.

We are a development stage company and have primarily supported the financial needs of our research and development activities since our inception through public offerings and private placements of our equity securities. We have not received any revenue from the sale of our products in development, and we do not anticipate generating revenue from the sale of products in the foreseeable future. As a result, we expect that we will need to obtain additional funding to support the anticipated future needs of our research and development activities, including the costs to complete clinical trials. We expect our source of revenue, if any, for the next several years to consist of payments under the Genzyme agreement, collaborative arrangements with third parties, government grants, and non-gene therapy-related license fees. We have incurred losses since our inception and expect to incur substantial losses over the next several years due to lack of any substantial revenue and the continuation of our ongoing and planned research and development efforts, including preclinical studies and clinical trials. There can be no assurance that we will successfully develop, commercialize, manufacture, or market our product candidates or ever achieve or sustain product revenue for profitability. At December 31, 2005 we had an accumulated deficit of \$171.3 million and cash, cash equivalents, available-for-sale securities and restricted investments of approximately \$70.4 million. We believe that our capital resources at December 31, 2005, after considering our anticipated spending focus on our small molecule compound-based programs and away from gene therapy-related activities, will be adequate to fund our operating needs for approximately the next three years.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, valuation of investments in financial instruments, impairment of property and equipment, and recognition of research and development expenses. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described under Note 1 in the Notes to our Financial Statements, we believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements.

#### ***Revenue recognition***

We recognize revenue when the four basic criteria for revenue recognition as described in SEC Staff Accounting Bulletin No. 104, "Revenue Recognition" are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured.

We recognize non-refundable license or assignment fees, including development milestone payments associated with license or assignment agreements, for which we have no further significant performance obligations and no continuing involvement requirements related to product development, on the earlier of the dates on when the payments are received or when collection is assured. For example, in connection with the \$12.0 million payment received under the terms of the Genzyme agreement, we concluded that as of December 31, 2005, we did not have any significant performance obligations under the agreement that would defer the completion of the earnings process, and so recognized the entire \$12.0 million payment received as revenue at that time.

We recognize revenue associated with up-front license, technology access and research and development funding payments under collaborative agreements ratably over the relevant periods specified in the agreements, generally the development phase. This development phase can be defined as a specified period of time, however, in certain cases, the collaborative agreement specifies a development phase that culminates with milestone objectives but does not have a fixed date and requires us to estimate the time period over which to recognize this revenue. Our estimated time periods are based on management's estimate of the time required to achieve a particular development milestone considering the projected level of effort and current stage of development. If our estimate

of the development-phase time period changes, the amount of revenue we recognize related to up-front payments for a given period will accelerate or decrease accordingly. For example, in March 2003, we received a \$2.5 million payment from Bayer under the terms of a collaboration agreement for Coagulin-B, a gene therapy product candidate for hemophilia. The revenue associated with the payment was being recognized ratably over the development phase, which was initially estimated to be five years. In May 2004, we suspended subject enrollment in the phase I clinical trial for this product candidate and, as a result, ended the development phase for this product candidate and recognized as revenue \$2.0 million, constituting the portion of the \$2.5 million payment not previously recognized as revenue, during the quarter ended June 30, 2004.

#### ***Valuation of investments in financial instruments***

We carry investments in financial instruments at fair value with unrealized gains and losses included in accumulated other comprehensive income or loss in stockholders' equity. Our investment portfolio does not include equity securities or derivative financial instruments that could subject us to material market risk; however, we do invest in corporate obligations that subject us to varying levels of credit risk. Management assesses whether declines in the fair value of investment securities are other-than-temporary. If a decline in fair value of a financial instrument is judged to be other-than-temporary, the cost basis of the individual security is written down to fair value and the amount of the write down is included in earnings. In determining whether a decline is other-than-temporary, management considers:

- the length of time and the extent to which the market value of the security has been less than cost;
- the financial condition and near-term prospects of the issuer; and
- our intention and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value, which could be until maturity.

The determination of whether a decline in fair value is other-than-temporary requires significant judgment, and could have a material impact on our balance sheet and results of operations. We have not had any write-downs for other-than-temporary declines in the fair value of our financial instruments since our inception.

In addition, when management commits to holding individual securities until maturity in order to avoid the recognition of an other-than-temporary impairment, those securities would no longer be classified as available-for-sale. In addition, such securities would be further evaluated to determine whether the security, based on the remaining duration until its scheduled maturity, should be identified as a current or long-term asset. As of December 31, 2005, management had not designated any individual securities as held-to-maturity for the purposes of avoiding an other-than-temporary impairment.

#### ***Impairment of property and equipment***

We have invested significant amounts on construction for improvements to leased facilities we use for our research and development activities, with the largest portion of our spending made to modify manufacturing facilities that are intended to comply with requirements of government mandated manufacturing rules for pharmaceutical production. Management assesses whether the carrying value of long-lived assets is impaired whenever events or changes in circumstances indicate that the asset may not be fully recoverable. An impairment loss is recognized when the total of the estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying value or appraised value, as appropriate. If the value of our long-lived assets is judged to be impaired, the cost basis of the property and equipment is written down to fair value and the amount of the write down is included in net loss from operations. In determining whether the value of our property and equipment is impaired, management considers:

- failure of manufacturing facilities and equipment to comply with government mandated policies and procedures;
- failure of the product candidates for which the manufacturing facilities have been constructed to receive regulatory approval; and
- the extent that facilities could be idled or abandoned due to a decrease in the scope of our research and development activities for an other-than-temporary period, resulting in excess capacity.

The determination of whether the value of our property and equipment is impaired requires significant judgment, and could have a material impact on our balance sheet and results of operations. During 2005, we determined that the scope of our research and development activities had changed such that we would not effectively utilize certain portions of our leased facilities that had been designed to support our gene therapy programs. After considering alternative uses for these spaces, we decided it was not cost effective to re-engineer the rooms representing approximately 40,000 square feet of manufacturing, laboratory, and office space under lease through May 2008 and approximately 11,000 square feet of similar space we have under lease through November 2010. We believe we would maximize our potential cost savings by subleasing the properties. Based on market conditions for rental property at the time of the reduction in the scope of our research and development activities, and our subsequent completion of sublease agreements for approximately 26,000 square feet, we do not expect to fully recover the value invested in leasehold improvements and equipment, and have reduced our net carrying value for these assets to their current fair value, resulting in an impairment loss for the year ended December 31, 2005 of approximately \$6.1 million. This amount does not impact our cash flows and primarily represents an acceleration of depreciation charges that would have been recognized over the remaining three and five year lease periods.

### ***Recognition of Research and Development Expenses***

Research and development expenses consist of expenses incurred in performing research and development activities including related salaries and benefits, facilities and other overhead costs, clinical trial and related drug product costs, contract services and other outside service expenses. Research and development expenses are charged to operating expense in the period incurred and consist of costs incurred for our independent, as well as our collaborative, research and development activities.

Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, we recognize expenses as the services are provided. Several of our contracts extend across multiple reporting periods. Management assessments include, but are not limited to an evaluation by the project manager of the work that has been completed during the period, measurement of progress prepared internally, estimates of incurred costs by the third-party service providers, and management's judgment. The determination of the percentage of work completed that determines the amount of research and development expense that should be recognized in a given period requires significant judgment, and could have a material impact on our balance sheet and results of operations. These estimated expenses may or may not match the actual fees billed by the service providers as determined by actual work completed. We monitor service provider activities to the extent possible; however, if we underestimate activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future reporting periods.

### **Results of Operations**

#### ***Revenue***

<u>(In thousands, except percentages)</u>	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Revenue .....	\$12,026	\$2,195	\$463
Percentage increase over prior period .....	448%	374%	

Revenue in 2005 primarily reflected the \$12.0 million payment received in connection with our agreement with Genzyme Corporation. Revenue in 2004 primarily included the acceleration of deferred revenue associated with the termination of our gene therapy collaboration with Bayer Corporation for hemophilia. We had received a \$2.5 million payment from Bayer in March 2003 in connection with our collaboration on a gene therapy product for hemophilia. The payment was being recognized ratably over the estimated development period of the product candidate, which was estimated at five years. In May 2004, we suspended patient enrollment in the trial, which resulted in the termination of the development of the product candidate and accelerated the recognition of all remaining deferred revenue.

Research license fees associated with our gene therapy technologies totaled \$22,500, \$64,500 and \$79,000, during 2005, 2004, and 2003, respectively. These research license agreements allowed licensees to make or use products using our patented AAV technologies for research purposes only, and did not allow for the use of these

technologies in products for commercial sale. Royalty revenue totaled \$3,200, \$5,800 and \$9,000 during 2005, 2004, and 2003, respectively, and was attributed to a single royalty license that was entered into in July 2000, which allowed for the development, manufacture, use and commercial sale of research products using our patented AAV technologies.

As a result of the assignment of our gene therapy assets to Genzyme, and termination of the collaboration agreement with Bayer in 2004, we are no longer a direct party to most of the license or collaboration agreements that gave rise to the revenues we recognized over the last three years. As a result, we do not expect any significant revenues for the foreseeable future and that such revenues, if any, will consist solely of payments that may be received in connection with the Genzyme agreement and other non-gene-therapy related activities.

#### *Research and Development Expenses*

Our research and development expenses can be divided into two primary functions, costs to support research and preclinical development and costs to support preparation for and implementation of human clinical trials. Research and preclinical development costs include activities associated with general research and exploration, animal studies, production of drug substances for use by external collaborators in general research and exploration, development of processes to translate research achievements into commercial scale capabilities, and in-house and independent third-party validation testing of potential acquisition or in-license drug candidates. Clinical development costs include activities associated with preparing for regulatory approvals, maintaining regulated and controlled processes, manufacturing drug substances for use in human clinical trials, and supporting subject enrollment and subject administration within clinical trials.

During the first half of 2004, our research and development activities were primarily focused on our AAV-based programs for hemophilia and Parkinson's disease and our non-AAV programs for neuropathic pain. Our staff count dedicated to research and development activities at the time averaged approximately 76 employees. In July 2004, in connection with the suspension of a gene therapy-related clinical trial for hemophilia, we began to shift the focus of our resources toward neurological programs, and reduced our workforce by approximately 36 percent. This reduced the number of employees dedicated to our research and development activities to approximately 45 at December 31, 2004. In August 2005, we took additional steps to reduce our involvement with and spending on AAV-based activities and reduced our workforce by approximately 19 positions, or 33 percent. As a result, at December 31, 2005, the staff count associated with our current research and development activities, which focus on our portfolio of small molecule candidates for the treatment of serious neurological and neuromuscular disorders, was approximately 20.

The costs associated with these two primary functions of our research and development activities approximate the following:

(In thousands, except percentages)	Year Ended December 31,		Percentage decrease 2005 over 2004	Year Ended December 31,	
	2005	2004		2003	Percentage decrease 2004 over 2003
Research and preclinical development .....	\$ 9,350	\$12,612	(26)%	\$13,450	(6)%
Clinical development .....	4,425	6,732	(34)%	8,355	(19)%
Total research and development expenses ..	<u>\$13,775</u>	<u>\$19,344</u>	<u>(29)%</u>	<u>\$21,805</u>	<u>(11)%</u>

Because a significant percentage of our research and development resources are dedicated to activities that focus on broad methods and mechanisms that may be used in multiple product applications, including production and administration techniques, the majority of our costs are not directly attributed to individual development programs. Decisions regarding our project management and resource allocation are primarily based on interpretations of scientific data, rather than cost allocations. Our estimates of costs between research and preclinical development and clinical development are primarily based on staffing roles within our research and development departments. As such, costs allocated to specific projects may not necessarily reflect the actual costs of those efforts and, therefore, we do not generally evaluate actual costs-incurred information on a project-by-project basis. In addition, we are unable to estimate the future costs to completion for any specific projects.

### Research and preclinical development

(In thousands)	Year Ended December 31,		
	2005	2004	2003
Personnel-related .....	\$2,938	\$ 4,880	\$ 5,015
External research and development .....	582	1,544	2,113
Other expenses including facilities overhead and depreciation .....	5,830	6,188	6,322
Total research and preclinical development expenses .....	<u>\$9,350</u>	<u>\$12,612</u>	<u>\$13,450</u>

*Comparison of Years Ended December 31, 2005 and 2004.* The decreases in our total research and preclinical development expenses for the year ended December 31, 2005, compared to 2004, of \$3.3 million, were primarily due to changes in costs for the following:

- lower personnel-related expenses of \$1.9 million, reflecting the impact of a significantly lower average staff level as a result of staff reductions in July 2004 and August 2005, partially offset by higher average salaries and higher severance expense in 2005,
- lower expenditures for external research and development services from third-party collaborators associated with our preclinical animal studies of \$1.0 million, primarily related to our completion of significant preclinical work with Parkinson's disease in 2004 as it transitioned into a clinical development phase, and
- lower other expenses of \$358,000, primarily reflecting a decrease in depreciation charges as a result of the write-down of the cost basis of our long-lived assets during the year due to impairment.

*Comparison of Years Ended December 31, 2004 and 2003.* The decreases in our total research and preclinical development expenses for the year ended December 31, 2004, compared to 2003, of \$838,000, were primarily due to changes in costs for the following:

- lower expenditures for external research and development services from third-party collaborators associated with our preclinical animal studies of \$569,000, primarily related to our completion of a significant portion of our preclinical work with Parkinson's disease in 2003 and a reduction in preclinical work associated with other gene therapy projects, primarily due to our lower staff levels in 2004,
- lower personnel-related expenses of \$135,000, primarily reflecting a lower average staff count as a result of the staff reduction in July 2004 and lower recruiting and relocation expenses reflecting a decline in hiring and the use of relocation payment incentives in 2004 compared to 2003, partially offset by higher severance expenses paid to employees affected by the staff reduction in 2004 and higher bonus expenses in 2004, and
- lower other expenses of \$134,000, primarily reflecting lower materials expenses due to a decrease in our consumption of materials to produce AAV vectors and support our other on-going research activities as a result of the transfer of our Parkinson's program into a clinical development phase, and the general impact of our lower staff levels in 2004.

### Clinical development

(In thousands)	Year Ended December 31,		
	2005	2004	2003
Personnel-related .....	\$1,343	\$2,189	\$2,709
External research and development .....	543	660	435
Other expenses including facilities overhead and depreciation .....	2,539	3,883	5,211
Total clinical development expenses .....	<u>\$4,425</u>	<u>\$6,732</u>	<u>\$8,355</u>

*Comparison of Years Ended December 31, 2005 and 2004.* The decreases in our total clinical development expenses for the year ended December 31, 2005, compared to 2004, of \$2.3 million, were primarily due to changes in costs for the following:

- lower personnel-related expenses of \$846,000, reflecting a significantly lower average staff level as a result of staff reductions in July 2004 and August 2005 and lower severance-related costs, partially offset by higher average salaries in 2005, and
- lower other expenses of \$1.3 million, primarily due to a decrease in depreciation charges as a result of the write-down of the cost basis of our long-lived assets during the year due to impairment, a decrease in the amounts of materials consumed in 2005 compared to the prior year in connection with the production of clinical-grade AAV vectors to support the needs of our clinical trials, and a decrease in other costs associated with our transition out of gene-therapy related activities.

*Comparison of Years Ended December 31, 2004 and 2003.* The decreases in our total clinical development expenses for the year ended December 31, 2004, compared to 2003, of \$1.6 million, were primarily due to changes in costs for the following:

- lower other expenses of \$1.3 million, primarily reflecting lower license origination fees, including \$97,000 of non-cash charges in connection with the issuance of warrants in 2003, and lower materials expenses reflecting lower levels of material consumed in 2004 for the production of clinical grade AAV vectors due to the delayed needs of our development programs at the clinical development stage, and
- lower personnel-related expenses of \$520,000, reflecting a lower average staff level, partially offset by higher severance expenses paid to employees affected by the staff reduction in 2004,

partially offset by,

- higher expenditures for external clinical development services from third-party collaborators associated with recruiting and treating subjects in our clinical trials of \$225,000, primarily related to regulatory costs associated with the filing for FDA approval and recruiting of our first subject in our phase I/II clinical trial for AV201, our gene-therapy-based product candidate for the treatment of Parkinson's disease.

Total research and development expenses for 2005 were within management's expectations, taking into account the scheduled pace of subject recruitment in our gene therapy-based Parkinson's disease clinical trial and the lengthy time periods common to negotiations with external parties. We believe delays in regulatory approvals and scheduling of participants will continue to be factors that could limit the pace of progress in future clinical trials for our portfolio of small molecule product candidates, albeit to a lesser degree than we experienced with gene therapy clinical trials. As a result, we have taken steps to reduce our overhead and operating costs in order to extend the life of our financial resources. If we are successful in our efforts to develop our product candidates, including the initiation of clinical trials, or acquire or in-license additional product candidates for development, our total research and development spending in 2006 will be likely to remain the same or rise in order to meet the development needs of such product candidates.

#### *General and Administrative Expenses*

(In thousands, except percentages)	Year Ended December 31,		
	2005	2004	2003
Personnel-related .....	\$3,434	\$3,162	\$3,244
Legal and professional fees .....	2,219	1,450	1,497
Non-recurring severance .....	22	1,022	—
Other expenses including facilities overhead and depreciation .....	2,589	2,733	2,658
Total general and administrative expenses .....	<u>\$8,264</u>	<u>\$8,367</u>	<u>\$7,399</u>
Percentage (decrease) increase over prior period .....	<u>(1%)</u>	<u>13%</u>	

*Comparison of the Years Ended December 31, 2005 and 2004.* The decrease of \$103,000 in our general and administrative expenses in 2005, compared to 2004, was primarily due to changes in costs for the following:

- lower severance expenses of \$1.0 million, primarily related to severance expense accrued in March 2004 in connection with the resignation of our former CEO, and
- lower other expenses of \$144,000, including savings from lower corporate insurance premiums, partially offset by,
- higher legal and professional fees of \$769,000, primarily related to an increase in costs associated with being a public company and increased use of third-party business consultants, and
- higher personnel-related expenses of \$272,000, reflecting higher average salaries and bonuses, partially offset by a slightly lower staff level in 2005.

*Comparison of the Years Ended December 31, 2004 and 2003.* The increase of \$968,000 in our general and administrative expenses in 2004, compared to 2003, was primarily due to severance expense of \$1.0 million, approximately \$900,000 of which was accrued in connection with the resignation of our former CEO in March 2004.

We expect our general and administrative expenses for 2006 to decrease below our 2005 levels, primarily due to lower average staff and overhead costs. However, if we are successful in the clinical development of our products, including increasing awareness of the market potential for our drug candidates, or expand our portfolio of development candidates through additional strategic relationships and collaborations, our expected general and administrative spending levels may increase in connection with the changing needs of the company.

#### *Impairment Loss Related to Long-Lived Assets*

(In thousands)	Year Ended December 31,		
	2005	2004	2003
Impairment loss related to long-lived assets .....	\$6,130	\$—	\$—

The carrying value of long-lived assets is reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss is recognized when the total of estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount or appraised value, as appropriate.

During 2005, we recorded impairment charges of \$6.1 million related to leasehold improvements and equipment associated with approximately 40,000 square feet of manufacturing, laboratory, and office space under lease through May 2008 and approximately 11,000 square feet of similar space we have under lease through November 2010. These charges were based on our assessments of changes in the scope of our research and development activities at June 30 and September 30, 2005, and the determination that it was not cost effective to re-engineer facilities that had been designed to support our AAV-based gene therapy programs. Based on these assessments, we have consolidated our operations and entered into sublease agreements for portions of these facilities. Under rental market conditions at the time of each assessment, we determined we would not receive incremental rents above the cost of our underlying lease obligations. Therefore, we adjusted the cost basis of the long-lived assets associated with these facilities to zero, to reflect their estimated fair value. These charges do not impact our cash flow and represent an acceleration of depreciation expenses that were scheduled to be recognized over the next three to five years. As a result of the recognition of these charges, future depreciation expenses for these long-lived assets will decrease.

#### *Interest Income*

(In thousands, except percentages)	Year Ended December 31,		
	2005	2004	2003
Interest income .....	\$1,682	\$1,905	\$3,282
Percentage decrease over prior period .....	(12%)	(42%)	

Almost all of our interest income is generated from our investments in high-grade marketable securities of government and corporate debt. The decline in interest income between 2005 and 2004 was primarily due to the

decrease in our outstanding interest-bearing cash and securities balances, due to the use of such resources to fund our on-going operations during the year, partially offset by a rising average yield earned on our portfolio of investments. The decline in interest income between 2004 and 2003 was due to the decrease in our outstanding interest-bearing cash and securities balance combined with a declining average yield earned on our portfolio of investments during the period.

#### ***Recently Issued Accounting Standards***

See Note 1, "Summary of Significant Accounting Policies — *New Accounting Pronouncements*," in the Notes to Consolidated Financial Statements for a discussion of recent accounting pronouncements and their effect, if any, on Avigen, which discussion is incorporated by reference here.

#### ***Deferred Income Tax Assets***

In accordance with FAS 109, "*Accounting for Income Taxes*," which is described in the Notes to our Financial Statements, we have calculated a deferred tax asset based on the potential future tax benefit we may be able to realize in future periods as a result of the significant tax losses experienced since our inception. However, the value of such deferred tax asset must be calculated using the tax rates expected to apply to the taxable income in the years in which such income occurs. Since we have no history of earnings, and cannot reliably predict when we might create taxable income, if at all, we have recorded a valuation allowance for the full amount of our calculated deferred tax asset.

#### ***Liquidity and Capital Resources***

Since our inception in 1992, cash expenditures have significantly exceeded our revenue. We have funded our operations primarily through public offerings and private placements of our equity securities. After our initial public offering in May 1996, we raised \$189 million from private placements and public offerings of our common stock and warrants to purchase our common stock. After our initial public offering, we also received additional funds as a result of exercises of previously issued warrants and options to purchase our common stock, including an additional \$1.5 million during the three-year-period ended December 31, 2005. The timing of and amounts realized from the exercise of these warrants and options are determined by the decisions of the respective warrant and option holders, and are not controlled by us. Therefore, funds received from exercises of stock options and warrants in past periods should not be considered an indication of additional funds to be received in the future periods. In addition, a significant percentage of options and warrants currently outstanding have exercise prices that exceed the current trading price of our common stock, and so unless the trading price of our common stock increases significantly, those options and warrants may never be exercised.

In addition to funding our operations through sales of our common stock, in March 2003, we received \$2.5 million in research support from Bayer Corporation in connection with our collaboration on a gene therapy product for hemophilia. In December 2005, we received a \$12.0 million payment from Genzyme Corporation in connection with the agreement transferring to Genzyme rights to most of our AAV-based intellectual property, our gene therapy clinical trial programs for Parkinson's disease and hemophilia, and clinical-grade vector materials.

We also have attempted to contain costs and reduce cash flow requirements by renting facilities, contracting with third parties to conduct research and development and using consultants, where appropriate. We expect to incur additional future expenses, resulting in significant additional cash expenditures, as we continue our research and development activities, including our efforts to develop, manufacture, and commercialize our current drug candidates, expand our product portfolio with additional development candidates through internal research, acquisition or in-licensing, and undertake additional preclinical studies and clinical trials of our product candidates. We also expect to incur substantial additional expenses relating to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims.

At December 31, 2005, we had cash, cash equivalents, available-for-sale securities, and restricted investments, of approximately \$70.4 million, compared to approximately \$76.2 million at December 31, 2004 and \$98.9 million at December 31, 2003. At December 31, 2005, 2004 and 2003, \$10.4 million, \$11.9 million, and \$11.9 million, respectively, of restricted investments were pledged to secure certain long-term liabilities. The reduction of

\$1.5 million in restricted investments at December 31, 2005, was directly associated with the reduction in our pledge to collateralize certain equipment operating leases. At December 31, 2005 and 2004, the portion of our investment portfolio pledged as collateral, which we refer to as restricted investments, includes \$10.0 million for our line of credit and approximately \$428,000 for letters of credit which serve as security deposits on a building lease. Our restricted investments would not be considered a current source of additional liquidity.

*Operating Activities.* Net cash used for operating activities was \$6.0 million for 2005 compared to \$21.8 million for 2004. The decrease in cash used for operating activities is primarily due to the receipt of \$12.0 million in 2005 in connection with our transaction with Genzyme, and \$5.6 million in lower 2005 research and development expenses as described previously.

Net cash used for operating activities in 2004 was \$21.8 million compared to \$19.3 million for 2003. The increase in the amount of cash used in 2004 compared to 2003 is primarily due to the \$2.5 million payment received from Bayer in 2003 in connection with our collaboration agreement.

The cash used in operating activities for these years was primarily used to support our internal research and development activities, as well as preclinical studies and clinical trials performed by third parties, and our evaluation of potential in-license product opportunities. The level of cash used in operating activities in 2005 was in line with management's expectations. The level of cash used for operating activities during 2004 was slightly lower than management's expectations due to the general delays in the progress of our clinical trials.

*Investing and Financing Activities.* Net cash provided by investing and financing activities in 2005 was \$14.0 million and \$286,000, respectively, compared to \$22.1 million and \$512,000, respectively, for the same activities in 2004. The cash provided by investing activities consisted primarily of sales and maturities, net of purchases, of available-for-sale securities and the reduction in restricted investments, offset to a small degree by purchases of property and equipment of \$277,000 in 2005 and \$467,000 in 2004. During 2005, cash provided by investing activities also included \$182,000 proceeds from our sale of laboratory and office equipment and furniture in connection with our consolidation of facilities previously used for our gene therapy activities. The cash provided by financing activities consisted of proceeds from the exercise of stock options and warrants during the period.

Net cash provided by investing and financing activities in 2003 was \$13.1 million and \$718,000, respectively. The cash provided by investing activities consisted primarily of sales and maturities, net of purchases, of available-for-sale securities, offset to a small degree by purchases of property and equipment of \$555,000 and an increase in restricted investments of \$428,000. The cash provided by financing activities consisted of proceeds from the exercise of stock options and warrants during the period.

During 2005, in connection with our decision to discontinue funding of our gene therapy programs, we took steps to reduce expenses by reducing our staff level and consolidating our operations in order to reduce overhead and sublease portions of our facilities. At December 31, 2005, we had reduced our full-time employee staff level to 35 from 60 at the end of the previous year, and completed sublease agreements for approximately 26,250 square feet of our leased facilities, or 23 percent. We believe that the future annual savings in personnel costs, including salaries, benefits, and temporary staffing, related to the impact of the August 2005 staff reduction will approximate \$2.2 million per year, and that the sum of scheduled sublease income and related reimbursement of a portion of our facilities overhead costs from our subtenants will approximate \$3.7 million over the remaining lease terms.

The following are contractual commitments at December 31, 2005 associated with debt obligations, lease obligations net of sublease income, and contractual commitments to fund third-party research (in thousands):

<u>Contractual Commitment</u>	<u>Payments Due by Period</u>			
	<u>Total</u>	<u>Less than 1 year</u>	<u>2-3 years</u>	<u>4-5 years</u>
Operating leases .....	\$10,153	\$2,437	\$ 4,550	\$3,166
Sublease income .....	(1,989)	(532)	(966)	(491)
Net operating leases .....	8,164	1,905	3,584	2,675
Revolving line of credit .....	8,000	—	8,000	—
Research funding for third-parties .....	510	510	—	—
Total .....	<u>\$16,674</u>	<u>\$2,415</u>	<u>\$11,584</u>	<u>\$2,675</u>

In June 2004, we amended the terms of our \$10.0 million revolving line of credit which had been put in place with Wells Fargo Bank in June 2000, to provide support for construction-related activities, and was subsequently amended in June 2002. Under the terms of the current amendment, the expiration date of the borrowing was extended from June 1, 2005 to June 1, 2007, thereby deferring the timetable to repay principal borrowed for two years. The debt instrument bears interest at a floating rate based on the London Inter-Bank Offered Rate, which is reset in three-month increments after the date of each drawdown, until such expiration. As of December 31, 2005 and 2004, the average annual rate of interest charged on the borrowing was approximately 4.97% and 2.70%, respectively. Also under the terms of this agreement, we pledged a portion of our portfolio of available for sale securities as collateral and have identified the amount of the pledged securities as restricted investments on our balance sheets. The amount of the pledged securities is equal to the amount of utilized borrowing capacity on the line of credit. At December 31, 2005, we had borrowed \$8.0 million from the line of credit and had reserved the remaining \$2.0 million in borrowing capacity to secure a letter of credit in connection with the property lease entered into in November 2000. As a result, at December 31, 2005, we have no more borrowing capacity under this facility.

Our current office and facility includes approximately 112,500 square feet of space. Of this, approximately 45,000 square feet of space is leased through May 2008 and approximately 67,500 square feet of space is leased through November 2010. We have completed sublease agreements for approximately 26,250 square feet of these leased facilities. Payments scheduled under these lease commitments and sublease agreements are included in the table above under operating leases and sublease income.

We enter into commitments to fund collaborative research and clinical work performed by third parties. While these contracts are cancelable by either party, we expect the research studies and clinical work to be completed as defined in the terms of the agreements, and all amounts paid when due. Payments scheduled to be made under these contracts are included in the table above under research funding for third-parties.

We believe we will continue to require substantial additional funding in order to complete the research and development activities currently contemplated and to commercialize our proposed products. We believe that with the reductions in our staff over the past two years, our efforts to reduce other legacy gene therapy-related spending, the receipt of \$12 million from Genzyme in connection with the assignment of rights to our gene therapy interests, and the consolidation of our operations and sublease of portions of our facilities, our financial resources at December 31, 2005 will be adequate to fund our projected operating needs for approximately three years. However, this forward-looking statement is based upon our current plans and assumptions regarding our future operating and capital requirements, which may change. Our future operating and capital requirements will depend on many factors, including:

- continued scientific progress in research and development programs;
- the scope and results of preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing, prosecuting and enforcing patents claims and other intellectual property rights;
- the costs involved in obtaining licenses to patented technologies from third-parties that may be needed to commercialize our product candidates;
- competing technological developments;
- the cost of manufacturing our product candidates for clinical trials and sales;
- the costs of marketing and commercialization activities;
- how successful, if at all, we are at acquiring or in-licensing additional compounds, and the nature of the consideration we pay for acquired or in-licensed compounds; and
- other factors which may not be within our control.

We intend to continue to seek additional funding through public or private equity or debt financing, when market conditions allow, or through additional collaborative arrangements with corporate partners. We may consider issuing equity securities under our October 2000 shelf registration statement. The balance of securities available for sale under

the existing shelf registration agreement is approximately \$26.4 million. If we raise additional funds by issuing equity securities, there may be further dilution to existing stockholders. We cannot assure our investors that we will be able to enter into such financing arrangements on acceptable terms or at all. Without such additional funding, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs.

**Item 7A. *Quantitative and Qualitative Disclosures About Market Risk***

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. We do not hold derivative financial investments, derivative commodity investments or other financial investments or engage in foreign currency hedging or other transactions that expose us to other market risks. None of our investments are held for trading purposes. Our investment objectives are focused on preservation of principal and liquidity. By policy, we manage our exposure to market risks by limiting investments to high quality issuers and highly liquid instruments with effective maturities of less than five years, and an average aggregate portfolio duration of approximately one to three years. Our entire portfolio is classified as available-for-sale and, as of December 31, 2005, consisted of 100% fixed-rate securities. This compares to approximately 95% fixed-rate securities and 5% variable-rate securities at December 31, 2004.

We have evaluated the risk associated with our portfolios of investments in marketable securities and have deemed this market risk to be immaterial. If market interest rates were to increase by 100 basis points, or 1%, from their December 31, 2005 levels, we estimate that the fair value of our securities portfolio would decline by approximately \$533,000. Our estimated exposure at December 31, 2005 is lower than our estimated \$740,000 exposure at December 31, 2004 due to the reduction in size of our overall portfolio. The modeling technique used measures duration risk sensitivity to estimate the potential change in fair value arising from an immediate hypothetical shift in market rates and quantifies the ending fair market value including principal and accrued interest.

Our long-term debt includes a \$10.0 million revolving line of credit due June 1, 2007, of which we have drawn down \$8.0 million in cash that will need to be repaid. Interest charged on the borrowing is based on LIBOR and is reset in three-month increments based on the date of each original drawdown. As of December 31, 2005, the average annual rate of interest charged on the borrowing was approximately 4.97% compared to 2.70% as of December 31, 2004.

**Item 8. *Financial Statements and Supplementary Data***

**INDEX TO FINANCIAL STATEMENTS**

The following financial statements are filed as part of this Report on Form 10-K. Condensed supplementary data for each of the quarters in the years ended December 31, 2005 and 2004 are set forth under Note 14 of our financial statements.

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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of Avigen, Inc.

We have audited the accompanying balance sheets of Avigen, Inc. (a development stage company) as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2005 and for the period from inception (October 22, 1992) through December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Avigen, Inc. at December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005 and for the period from inception (October 22, 1992) through December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Avigen Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2006 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 14, 2006

**Item 1. Financial Statements**

**AVIGEN, INC.**  
**(a development stage company)**

**BALANCE SHEETS**  
**(in thousands, except share and per share information)**

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents .....	\$ 11,510	\$ 3,217
Available-for-sale securities .....	48,450	61,073
Accrued interest .....	470	708
Prepaid expenses and other current assets .....	737	443
Total current assets .....	61,167	65,441
Restricted investments .....	10,428	11,928
Property and equipment, net .....	3,929	12,497
Deposits and other assets .....	740	641
Total assets .....	<u>\$ 76,264</u>	<u>\$ 90,507</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and other accrued liabilities .....	\$ 984	\$ 641
Accrued compensation and related expenses .....	534	927
Total current liabilities .....	1,518	1,568
Long-term loan payable .....	8,000	8,000
Deferred rent and other liabilities .....	1,282	1,064
Commitments		
Stockholders' equity:		
Preferred Stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding in 2005 and 2004 .....	—	—
Common Stock, \$0.001 par value, 50,000,000 shares authorized, and 20,907,273 and 20,381,250 shares issued and outstanding at December 31, 2005 and 2004, respectively .....	21	20
Additional paid-in capital .....	237,258	236,959
Accumulated other comprehensive loss .....	(540)	(525)
Deficit accumulated during development stage .....	(171,275)	(156,579)
Total stockholders' equity .....	65,464	79,875
Total liabilities and stockholders' equity .....	<u>\$ 76,264</u>	<u>\$ 90,507</u>

*See accompanying notes.*

**AVIGEN, INC.**  
(a development stage company)

**STATEMENTS OF OPERATIONS**  
(in thousands, except for share and per share information)

	Year Ended December 31,			Period from October 22, 1992 (inception) through December 31, 2005
	2005	2004	2003	
Revenue .....	\$ 12,026	\$ 2,195	\$ 463	\$ 15,471
Operating expenses:				
Research and development .....	13,775	19,344	21,805	141,280
General and administrative .....	8,264	8,367	7,399	60,454
Impairment loss related to long-lived assets ...	6,130	—	—	6,130
In-license fees .....	—	—	—	5,034
Total operating expenses .....	<u>28,169</u>	<u>27,711</u>	<u>29,204</u>	<u>212,898</u>
Loss from operations .....	(16,143)	(25,516)	(28,741)	(197,427)
Interest expense .....	(323)	(209)	(250)	(2,703)
Interest income .....	1,682	1,905	3,282	28,992
Other income (expense), net .....	88	(103)	(65)	(137)
Net loss .....	<u>\$ (14,696)</u>	<u>\$ (23,923)</u>	<u>\$ (25,774)</u>	<u>\$ (171,275)</u>
Basic and diluted net loss per common share ....	<u>\$ (0.71)</u>	<u>\$ (1.17)</u>	<u>\$ (1.28)</u>	
Shares used in basic and diluted net loss per common share calculation .....	<u>20,624,229</u>	<u>20,362,155</u>	<u>20,149,214</u>	

*See accompanying notes.*

**AVIGEN, INC.**  
(a development stage company)

**STATEMENTS OF STOCKHOLDERS' EQUITY**

Period from October 22, 1992 (inception) through December 31, 2005  
(in thousands, except for share information)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Class B Convertible Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Paid-in Capital</u>	<u>Other Comprehensive Gain (Loss)</u>	<u>Accumulated During the Development Stage</u>	<u>Stockholders' Equity</u>
Balance at October 22, 1992 (inception) .....	—	\$—	—	\$—	—	\$—	\$ —	\$—	\$ —	\$ —
Issuance of common stock at \$0.004 per share in November and December 1992 .....	—	—	896,062	1	—	—	4	—	—	5
Issuance of common stock at \$0.554 per share from January to June 1993 for services rendered .....	—	—	20,316	—	—	—	11	—	—	11
Issuance of common stock at \$0.004 to \$0.222 per share from November 1992 to March 1993 for cash .....	—	—	1,003,406	1	—	—	54	—	—	55
Issuance of Class B common stock at \$0.004 per share in December 1992 for cash .....	—	—	—	—	90,293	—	1	—	—	1
Issuance of Series A preferred stock at \$4.43 per share from March to June 1993 for cash (net of issuance costs of \$410,900) .....	678,865	1	—	—	—	—	2,595	—	—	2,596
Issuance of Series A preferred stock at \$3.85 per share in March 1993 for cancellation of note payable and accrued interest .....	68,991	—	—	—	—	—	266	—	—	266
Issuance of common stock at \$0.004 per share in November 1993 pursuant to antidilution rights .....	—	—	22,869	—	—	—	1	—	—	1
Issuance of Series A preferred stock at \$4.43 per share from July to November 1993 for cash and receivable (net of issuance costs of \$187,205) ...	418,284	—	—	—	—	—	1,665	—	—	1,665
Issuance of Series B preferred stock at \$5.54 per share in March 1994 for cash (net of issuance costs of \$34,968) ....	128,031	—	—	—	—	—	674	—	—	674
Issuance of Series C preferred stock at \$4.87 per share from July 1994 to June 1995 for cash and receivables (net of issuance costs of \$259,620) ...	739,655	1	—	—	—	—	3,344	—	—	3,345
Issuance of Series C preferred stock at \$4.87 per share in June 1995 for cancellation of notes payable .....	35,500	—	—	—	—	—	173	—	—	173
Net loss and comprehensive loss from inception to June 30, 1995 .....	—	—	—	—	—	—	—	—	(8,608)	(8,608)
Balance at June 30, 1995 (carried forward) .....	2,069,326	\$ 2	1,942,653	\$ 2	90,293	\$—	\$8,788	\$—	\$(8,608)	\$ 184

*See accompanying notes.*

**AVIGEN, INC.**  
(a development stage company)

**STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)**

Period from October 22, 1992 (inception) through December 31, 2005  
(in thousands, except for share information)

	Preferred Stock		Common Stock		Class B Convertible Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at June 30, 1995 (brought forward) .....	2,069,326	\$ 2	1,942,653	\$ 2	90,293	\$—	\$ 8,788	\$—	\$ (8,608)	\$ 184
Issuance of Series C preferred stock at \$4.87 per share in July 1995 for cash (net of issuance costs of \$26,000) .....	41,042	—	—	—	—	—	174	—	—	174
Issuance of Series D preferred stock at \$7.09 per share from October 1995 to February 1996 for cash (net of issuance costs of \$25,279) .....	205,351	—	—	—	—	—	1,430	—	—	1,430
Issuance of Series D preferred stock at \$7.09 per share in March 1996 in settlement of accounts payable .....	22,574	—	—	—	—	—	160	—	—	160
Issuance of common stock at \$.004 per share in March 1996 pursuant to antidilution rights ..	—	—	17,630	—	—	—	1	—	—	1
Issuance of stock options in February 1996 in settlement of certain accrued liabilities .....	—	—	—	—	—	—	137	—	—	137
Conversion of Class B common stock to common stock .....	—	—	231,304	1	(90,293)	—	(1)	—	—	—
Issuance of warrants to purchase common stock in connection with 1996 bridge financing in March 1996 .....	—	—	—	—	—	—	300	—	—	300
Conversion of preferred stock to common stock in May 1996 ..	(2,338,293)	(2)	2,355,753	2	—	—	(1)	—	—	(1)
Issuance of common stock at \$8.00 per share in connection with the May 1996 initial public offering (net of issuance costs of \$798,414 and underwriting discount of \$1,500,000) .....	—	—	2,500,000	2	—	—	17,699	—	—	17,701
Proceeds from exercise of options at \$0.44 per share in June 1996 ..	—	—	6,178	—	—	—	3	—	—	3
Repurchase of common stock ..	—	—	(18,325)	—	—	—	(1)	—	—	(1)
Deferred compensation .....	—	—	—	—	—	—	164	—	—	164
Amortization of deferred compensation .....	—	—	—	—	—	—	(128)	—	—	(128)
Net loss and comprehensive loss ..	—	—	—	—	—	—	—	—	(4,097)	(4,097)
Balance at June 30, 1996 (carried forward) .....	—	\$—	7,035,193	\$ 7	—	\$—	\$28,725	\$—	\$(12,705)	\$16,027

*See accompanying notes.*

**AVIGEN, INC.**  
(a development stage company)

**STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)**

Period from October 22, 1992 (inception) through December 31, 2005  
(in thousands, except for share information)

	Preferred Stock		Common Stock		Class B Convertible Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at June 30, 1996 (brought forward) .....	—	\$—	7,035,193	\$ 7	—	\$—	\$28,725	\$—	\$(12,705)	\$16,027
Issuance of common stock at \$8.00 per share in July 1996 in connection with the exercise of underwriters' over-allotment option (net of underwriting discount of \$150,000) .....	—	—	250,000	—	—	—	1,850	—	—	1,850
Proceeds from exercise of options at \$0.44 to \$0.71 per share ...	—	—	3,387	—	—	—	1	—	—	1
Amortization of deferred compensation .....	—	—	—	—	—	—	41	—	—	41
Net loss and comprehensive loss ..	—	—	—	—	—	—	—	—	(5,578)	(5,578)
Balance at June 30, 1997 .....	—	—	7,288,580	7	—	—	30,617	—	(18,283)	12,341
Proceeds from exercise of options at \$0.44 to \$0.71 per share ...	—	—	17,278	—	—	—	10	—	—	10
Amortization of deferred compensation .....	—	—	—	—	—	—	41	—	—	41
Compensation expense related to options granted for services ...	—	—	—	—	—	—	68	—	—	68
Net loss and comprehensive loss ..	—	—	—	—	—	—	—	—	(8,877)	(8,877)
Balance at June 30, 1998 .....	—	—	7,305,858	7	—	—	30,736	—	(27,160)	3,583
Proceeds from exercise of options at \$0.44 to \$4.31 per share ...	—	—	181,045	—	—	—	222	—	—	222
Amortization of deferred compensation .....	—	—	—	—	—	—	41	—	—	41
Issuance of common stock at \$2.25-\$2.94 per share and warrants in August to September 1998 in connection with a Private Placement (net of issuance cost of \$233,584) ..	—	—	1,306,505	1	—	—	2,734	—	—	2,735
Issuance of common stock at \$3.81-\$4.88 per share and warrants in December 1998 in connection with a Private Placement (net of issuance cost of \$438,183) .....	—	—	1,367,280	2	—	—	5,195	—	—	5,197
Issuance of common stock at \$5.50-\$6.00 per share and warrants in February to April 1999 in connection with a Private Placement (net of issuance cost of \$1,033,225) ..	—	—	2,198,210	2	—	—	12,154	—	—	12,156
Net loss and comprehensive loss ..	—	—	—	—	—	—	—	—	(9,611)	(9,611)
Balance at June 30, 1999 (carried forward) .....	—	\$—	12,358,898	\$12	—	\$—	\$51,082	\$—	\$(36,771)	\$14,323

*See accompanying notes.*

**AVIGEN, INC.**  
(a development stage company)

**STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)**

Period from October 22, 1992 (inception) through December 31, 2005  
(in thousands, except for share information)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Class B Convertible Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Other</u>	<u>Accumulated</u>	<u>Stockholders'</u>
							<u>Capital</u>	<u>Comprehensive</u>	<u>During the</u>	<u>Equity</u>
								<u>Gain (Loss)</u>	<u>Development</u>	
									<u>Stage</u>	
Balance at June 30, 1999										
(brought forward) .....	—	\$—	12,358,898	\$12	—	\$—	\$ 51,082	\$ —	\$(36,771)	\$ 14,323
Proceeds from exercise of options										
at \$0.44 to \$15.50 .....	—	—	440,259	1	—	—	1,533	—	—	1,534
Proceeds from exercise of										
warrants at \$2.81 to \$31.95 ...	—	—	1,017,215	1	—	—	8,427	—	—	8,428
Amortization of deferred										
compensation .....	—	—	—	—	—	—	5	—	—	5
Compensation expense related to										
options granted for services ...	—	—	—	—	—	—	89	—	—	89
Warrants granted for										
patent licenses .....	—	—	—	—	—	—	3,182	—	—	3,182
Warrants granted for										
building lease .....	—	—	—	—	—	—	1,738	—	—	1,738
Issuance of common stock at										
\$16.19 to \$25.56 per share										
and warrants in October and										
November 1999 in connection										
with a Private Placement (net										
of issuance cost of \$2,804,255)	—	—	2,033,895	2	—	—	37,220	—	—	37,222
Issuance of common stock at										
\$26 per share in April and										
May 2000 in connection with										
a Public Offering (net of										
issuance cost of \$2,288,966) ...	—	—	1,150,000	1	—	—	27,610	—	—	27,611
Comprehensive loss:										
Net loss .....	—	—	—	—	—	—	—	—	(15,039)	(15,039)
Net unrealized loss on										
available-for-sale securities...	—	—	—	—	—	—	—	(80)	—	(80)
Comprehensive loss .....	—	—	—	—	—	—	—	—	—	(15,119)
Balance at June 30, 2000										
(carried forward) .....	—	\$—	17,000,267	\$17	—	\$—	\$130,886	\$(80)	\$(51,810)	\$ 79,013

*See accompanying notes.*

**AVIGEN, INC.**  
(a development stage company)

**STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)**

Period from October 22, 1992 (inception) through December 31, 2005  
(in thousands, except for share information)

	Preferred Stock		Common Stock		Class B Convertible Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at June 30, 2000										
(brought forward) .....	—	\$—	17,000,267	\$17	—	\$—	\$130,886	\$ (80)	\$ (51,810)	\$ 79,013
Proceeds from exercise of options at \$0.44 to \$34.00 per share ..	—	—	165,700	—	—	—	869	—	—	869
Proceeds from exercise of warrants at \$2.18 to \$23.43 ...	—	—	174,255	1	—	—	771	—	—	772
Compensation expense related to options granted for services ...	—	—	—	—	—	—	336	—	—	336
Issuance of common stock at \$37.50 to \$45.06 per share in November 2000 Public Offering (net of issuance cost of \$4,622,188) .....	—	—	2,291,239	2	—	—	86,084	—	—	86,086
Issuance of common stock at \$47.82 per share in February 2001 pursuant to a collaboration agreement .....	—	—	313,636	—	—	—	15,000	—	—	15,000
Comprehensive loss:										
Net loss .....	—	—	—	—	—	—	—	—	(16,014)	(16,014)
Net unrealized gain on available-for-sale securities ..	—	—	—	—	—	—	—	1,120	—	1,120
Comprehensive loss .....	—	—	—	—	—	—	—	—	—	(14,894)
Balance at June 30, 2001 .....	—	—	19,945,097	20	—	—	233,946	1,040	(67,824)	167,182
Proceeds from exercise of options at \$2.13 to \$6.75 per share ...	—	—	11,282	—	—	—	60	—	—	60
Proceeds from exercise of warrants \$7.50 per share .....	—	—	9,955	—	—	—	75	—	—	75
Compensation expense related to options granted for services ...	—	—	—	—	—	—	179	—	—	179
Comprehensive loss:										
Net loss .....	—	—	—	—	—	—	—	—	(11,319)	(11,319)
Net unrealized gain on available-for-sale securities ..	—	—	—	—	—	—	—	1,173	—	1,173
Comprehensive loss .....	—	—	—	—	—	—	—	—	—	(10,146)
Balance at December 31, 2001 .....	—	—	19,966,334	20	—	—	234,260	2,213	(79,143)	157,350
Proceeds from exercise of options at \$1.875 to \$8.525 per share ..	—	—	34,627	—	—	—	113	—	—	113
Proceeds from exercise of warrants at \$7.50 per share ...	—	—	99,585	—	—	—	747	—	—	747
Compensation expense related to options granted for services ...	—	—	—	—	—	—	217	—	—	217
Comprehensive loss:										
Net loss .....	—	—	—	—	—	—	—	—	(27,739)	(27,739)
Net unrealized loss on available-for-sale securities ..	—	—	—	—	—	—	—	(631)	—	(631)
Comprehensive loss .....	—	—	—	—	—	—	—	—	—	(28,370)
Balance at December 31, 2002 (carried forward) .....	—	\$—	20,100,546	\$20	—	\$—	\$235,337	\$1,582	\$(106,882)	\$130,057

*See accompanying notes.*

**AVIGEN, INC.**  
(a development stage company)

**STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)**

Period from October 22, 1992 (inception) through December 31, 2005  
(In thousands, except for share information)

	Preferred Stock		Common Stock		Class B Convertible Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2002 (brought forward) .....	—	\$—	20,100,546	\$20	—	\$—	\$235,337	\$ 1,582	\$(106,882)	\$130,057
Proceeds from exercise of options at \$2.12 to \$6.50 per share ...	—	—	63,746	—	—	—	242	—	—	242
Proceeds from exercise of warrants at \$2.47 to \$6.09 per share .....	—	—	112,102	—	—	—	476	—	—	476
Compensation expense related to options granted for services ...	—	—	—	—	—	—	65	—	—	65
Comprehensive loss:										
Net loss .....	—	—	—	—	—	—	—	—	(25,774)	(25,774)
Net unrealized loss on available-for-sale securities ..	—	—	—	—	—	—	—	(1,180)	—	(1,180)
Comprehensive loss .....	—	—	—	—	—	—	—	—	—	(26,954)
Balance at December 31, 2003 .....	—	—	20,276,394	20	—	—	236,120	402	(132,656)	103,886
Proceeds from exercise of options at \$0.443 to \$6.313 per share ..	—	—	86,856	—	—	—	403	—	—	403
Proceeds from exercise of warrants at \$6.05 per share ...	—	—	18,000	—	—	—	109	—	—	109
Compensation expense related to options granted for services ...	—	—	—	—	—	—	230	—	—	230
Warrants granted for patent licenses .....	—	—	—	—	—	—	97	—	—	97
Comprehensive loss:										
Net loss .....	—	—	—	—	—	—	—	—	(23,923)	(23,923)
Net unrealized loss on available-for-sale securities ..	—	—	—	—	—	—	—	(927)	—	(927)
Comprehensive loss .....	—	—	—	—	—	—	—	—	—	(24,850)
Balance at December 31, 2004 .....	—	—	20,381,250	20	—	—	236,959	(525)	(156,579)	79,875
Proceeds from exercise of options at \$0.487 to \$3.53 per share ...	—	—	526,023	1	—	—	286	—	—	287
Compensation expense related to options granted for services ...	—	—	—	—	—	—	13	—	—	13
Comprehensive loss:										
Net loss .....	—	—	—	—	—	—	—	—	(14,696)	(14,696)
Net unrealized loss on available-for-sale securities ..	—	—	—	—	—	—	—	(15)	—	(15)
Comprehensive loss .....	—	—	—	—	—	—	—	—	—	(14,711)
Balance at December 31, 2005 .....	—	\$—	20,907,273	\$21	—	\$—	\$237,258	\$ (540)	\$(171,275)	\$ 65,464

*See accompanying notes.*

**AVIGEN, INC.**  
(a development stage company)

**STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31,			Period from October 22, 1992 (inception) through December 31, 2005
	2005	2004	2003	
<b>Operating Activities</b>				
Net loss	\$(14,696)	\$(23,923)	\$(25,774)	\$(171,275)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	2,549	3,610	3,640	18,526
Gain on disposal of property and equipment	(65)	—	—	(65)
Impairment loss related to long-lived assets	6,130	—	—	6,130
Amortization of deferred compensation	—	—	—	164
Non-cash rent expense for warrants issued in connection with the extension of the building lease	217	217	217	1,266
Amortization of deferred rent	3	97	115	954
Non-cash compensation expense for common stock, warrants, and stock options issued for services	13	230	65	1,718
Warrants issued for patent license	—	—	—	3,182
Changes in operating assets and liabilities:				
Accrued interest	238	66	219	(286)
Prepaid expenses and other current assets	(294)	1	14	(921)
Deposits and other assets	(316)	—	210	(342)
Accounts payable, other accrued liabilities and accrued compensation and related expenses	167	49	(160)	2,245
Deferred revenue	—	(2,125)	2,125	—
Net cash used in operating activities	\$(6,054)	\$(21,778)	\$(19,329)	\$(138,704)
<b>Investing Activities</b>				
Purchases of property and equipment	(277)	(467)	(555)	(28,455)
Proceeds from disposal of property and equipment	231	—	—	231
Decrease (increase) in restricted investments	1,500	—	(428)	(10,428)
Purchases of available-for-sale securities	(66,475)	(79,670)	(84,129)	(771,560)
Maturities of available-for-sale securities	79,082	102,236	98,228	722,571
Net cash provided by (used in) investing activities	14,061	22,099	13,116	(87,641)
<b>Financing Activities</b>				
Proceeds from long-term obligations	—	—	—	10,133
Repayment of long-term obligations	—	—	—	(1,710)
Proceeds from bridge financing	—	—	—	1,937
Repayment of bridge financing	—	—	—	(2,131)
Payments on capital lease obligations	—	—	—	(2,154)
Proceeds from sale-leaseback of equipment	—	—	—	1,927
Proceeds from issuance preferred stock, net of issuance costs	—	—	—	9,885
Proceeds from warrants and options exercised	286	512	718	14,349
Proceeds from issuance of common stock, net of issuance costs and repurchases	—	—	—	205,619
Net cash provided by financing activities	286	512	718	237,855
Net increase (decrease) in cash and cash equivalents	8,293	833	(5,495)	11,510
Cash and cash equivalents, beginning of period	3,217	2,384	7,879	—
Cash and cash equivalents, end of period	<u>\$ 11,510</u>	<u>\$ 3,217</u>	<u>\$ 2,384</u>	<u>\$ 11,510</u>
<b>Supplemental disclosure</b>				
Issuance of warrants in connection with building lease extension	\$ —	\$ —	\$ —	\$ 1,738
Issuance of preferred stock for cancellation of accounts payable, notes payable and accrued interest	—	—	—	499
Issuance of stock options for repayment of certain accrued liabilities	—	—	—	137
Issuance of warrants in connection with bridge financing	—	—	—	300
Issuance of warrants in connection with the extension of the building lease	—	—	—	1,738
Deferred compensation related to stock option grants	—	—	—	164
Purchase of property and equipment under capital lease financing	—	—	—	226
Cash paid for interest	\$ 323	\$ 209	\$ 250	\$ 2,210

*See accompanying notes.*

**AVIGEN, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**1. Summary of Significant Accounting Policies**

*Description of Business and Basis of Presentation*

Avigen, Inc. was incorporated on October 22, 1992 in Delaware and is focused on developing and commercializing small molecule therapeutics and biologics to treat serious neurological and neuromuscular disorders. Our current product candidates primarily address neuromuscular spasm and spasticity and neuropathic pain. Since our inception, our activities have consisted principally of acquiring product rights, raising capital, establishing facilities and performing research and development. Accordingly, we are considered to be in the development stage. We operate in a single segment.

At December 31, 2005, we had an accumulated deficit of \$171.3 million and expect to continue to incur substantial losses over the next several years while we continue in this development stage. Our operations are subject to certain risks and uncertainties frequently encountered by companies in the early stages of operations, particularly in the evolving market for small biotech and specialty pharmaceuticals companies. Such risks and uncertainties include, but are not limited to, timing and uncertainty of achieving milestones in clinical trials and in obtaining approvals by the FDA and regulatory agencies in other countries. Our ability to generate revenues in the future will depend substantially the timing and success of reaching development milestones and in obtaining regulatory approvals and market acceptance of our products, assuming the FDA approves our new drug applications. We plan to meet our future capital requirements primarily through issuances of equity securities, payments under collaborative agreements with third parties, government grants, and license fees. We intend to seek additional funding through public or private equity or debt financing, when market conditions allow. There can be no assurance that we will be able to enter into financing arrangements on acceptable terms in the future, if at all.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires our management to make judgments, assumptions and estimates that affect the amounts reported in our financial statements and the accompanying notes. Actual results could differ materially from those estimates.

*Cash and Cash Equivalents*

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. These amounts are recorded at cost, which approximates fair market value.

*Available-for-Sale Securities*

We invest our excess cash balances in marketable securities, primarily corporate debt securities, federal agency obligations, asset-backed securities, U.S. treasuries, and municipal bonds, with the primary investment objectives of preservation of principal, a high degree of liquidity, and maximum total return. All marketable securities are held in our name under the custodianship of Wells Capital Management. We have classified all our investments in marketable securities as available-for-sale. Available-for-sale securities are reported at market value and unrealized holding gains and losses, net of the related tax effect, if any, are excluded from earnings and are reported in other comprehensive income and as a separate component of stockholders' equity until realized. A decline in the market value of a security below its cost that is deemed to be other than temporary is charged to earnings, and would result in the establishment of a new cost basis for the security.

Our available-for-sale securities consist principally of obligations with a minimum short-term rating of A1/P1 and a minimum long-term rating of A- and with effective maturities of less than three years. The cost of securities sold is based on the specific identification method. Interest on securities classified as available for sale is included in interest income.

**AVIGEN, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS — (Continued)**

*Fair value of financial instruments*

The fair value of our cash equivalents and available-for-sale securities is based on quoted market prices. The fair value of our loans payable is based on current interest rates available to us for debt instruments with similar terms, degrees of risk, and remaining maturities. The carrying amount of our cash equivalents, available-for-sale securities and loan payable are considered to be representative of their respective fair value at December 31, 2005 and 2004.

*Restricted Investments*

In June 2000, we initially entered into a financing arrangement to support construction related activities. Under this arrangement, we have pledged \$10.0 million of our portfolio of available-for-sale securities to secure this long-term obligation.

In January 2002, we also entered into equipment operating leases for certain research and development equipment. Under the terms of these leases, we pledged \$1.5 million of our portfolio of available-for-sale securities to secure these equipment operating leases. These leases were terminated in December 2005 and the associated pledge removed.

In May 2003, we secured two letters of credit to serve as security deposits in connection with a building lease that became effective July 1, 2003. This building lease was executed in February 2000 and replaced our previous building lease and sublease on the same premises that expired June 30, 2003 under the original terms of the agreements. Under the terms of these letters of credit, we have pledged \$428,000 of our portfolio of available-for-sale securities to secure these letters of credit.

At December 31, 2005 and 2004, \$10.4 million and \$11.9 million, respectively, were classified as restricted investments in long term assets, representing the combined aggregate portion of our portfolio of available-for-sale securities that were pledged in connection with these long-term liabilities.

*Concentration of Credit Risk*

Cash, cash equivalents, available-for-sale securities and restricted investments consist of financial instruments that potentially subject us to concentrations of credit risk to the extent of the value of the assets recorded on the balance sheet. We believe that we have established guidelines for investment of our excess cash that maintain safety and liquidity through our policies on diversification among asset classes and issuers, as well as across investment maturities.

*Impairment of Long-Lived Assets*

All long-lived assets are reviewed for potential impairment whenever events or changes in business circumstances indicate that the carrying value of an asset may not be fully recoverable under Statement of Financial Account Standards No. 144 "Accounting for Impairment or Disposal of Long-Lived Assets." Impairment is determined by comparing future projected undiscounted cash flows to be generated by the asset to its carrying value. If impairment is identified, a loss would be recognized and reflected in net loss to the extent that the carrying amount of the asset exceeds its estimated fair value determined by discounted cash flow analyses or comparable fair valued or similar assets.

*Property and Equipment*

Property and equipment are stated at cost, less accumulated depreciation. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the respective assets, or in the case of leasehold improvements, over the lesser of the estimated useful lives or the remaining lease terms. The estimated useful lives of our property and equipment range from three to seven years.

**AVIGEN, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS — (Continued)**

Expenses for repairs and maintenance are charged to operations as incurred. Upon retirement, disposition, or sale, the cost of the property and equipment disposed of and the related accumulated depreciation are deducted from the accounts, and any resulting gain or loss is credited or charged to operations.

*Revenue Recognition*

We recognize revenue when the four basic criteria for revenue recognition as described in SEC Staff Accounting Bulletin No. 104, "Revenue Recognition" are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured.

*Revenues from the License or Assignment of Intellectual Property Rights*

We recognize non-refundable license or assignment fees, including development milestone payments associated with license or assignment agreements, for which we have no further significant performance obligations and no continuing involvement requirements related to product development, on the earlier of the dates on when the payments are received or when collection is assured.

*Revenues from Collaborative Research and Development Agreements*

We recognize fees associated with up-front license, technology access and research and development funding payments under collaborative agreements ratably over the relevant periods specified in the agreements, generally the development phase. This development phase can be defined as a specified period of time, however, in certain cases, the collaborative agreement specifies a development phase that culminates with milestone objectives but does not have a fixed date and requires us to estimate the time period over which to recognize this revenue. Our estimated time periods are based on management's estimate of the time required to achieve a particular development milestone considering the projected level of effort and current stage of development. If our estimate of the development-phase time period changes, the amount of revenue we recognize related to up-front payments for a given period will accelerate or decrease accordingly.

*Royalty Revenues*

We record royalty revenue from license agreements as earned in accordance with the contract terms when third-party results can be reliably determined and collectibility is reasonably assured. We have recorded approximately \$38,000 in royalty revenue since our inception in connection with sales from a third party of products that utilize our gene therapy technologies. These products were sold for research purposes only and were primarily sold within the U.S. As of December 31, 2005, we no longer were directly entitled to collect royalty revenue on these products under the license agreements under which we previously collected them. This is because we have assigned our rights under those agreements to Genzyme. However, we may be entitled to collect from Genzyme sublicensing fees and royalties on these products potentially at different or lower rates than we previously collected as a party to the third-party licenses.

*Grant Revenue*

We record grant revenue in the period in which the revenue is earned as defined by the grant agreement. Since our inception, we have recognized approximately \$690,000 of grant revenue, which includes amounts earned pursuant to reimbursements under government grants, of which all have come from the National Institutes of Health.

**AVIGEN, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS — (Continued)**

*Deferred Rent*

We record our obligations under facility operating lease agreements as rent expense. We recognize rent expense on a straight-line basis over the term of the operating lease. The difference in actual amounts paid and amounts recorded as rent expense during the fiscal year has been recorded as deferred rent. Amounts classified as deferred rent totaled \$1.1 million at both December 31, 2005 and 2004.

*Comprehensive Loss*

Components of other comprehensive loss, including unrealized gains and losses on available-for-sale investments, were included as part of total comprehensive loss. For all periods presented, we have disclosed comprehensive loss in the statement of stockholders' equity.

*Research and Development Expenses*

Research and development expenses consist of expenses incurred in performing research and development activities including related salaries and benefits, facilities and other overhead costs, clinical trial and related drug product costs, contract services and other outside service expenses. Research and development expenses are charged to operating expense in the period incurred and consist of costs incurred for our independent, as well as our collaborative, research and development activities.

Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, we recognize expenses as the services are provided. Several of our contracts extend across multiple reporting periods. Management assessments include, but are not limited to, an evaluation by the project manager of the work that has been completed during the period, measurement of progress prepared internally, estimates of incurred costs by the third-party service providers, and management's judgment. The determination of the percentage of work completed that determines the amount of research and development expense that should be recognized in a given period requires significant judgment, and could have a material impact on our balance sheet and results of operations. These estimated expenses may or may not match the actual fees billed by the service providers as determined by actual work completed. We monitor service provider activities to the extent possible; however, if we underestimated activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future reporting periods.

*Income Taxes*

Income taxes are accounted for in accordance with FAS 109, *Accounting for Income Taxes*, which requires the use of the liability method. Deferred tax assets and liabilities are provided for temporary differences between the financial reporting and the tax bases of existing assets and liabilities. To date, we have no history of earnings. Therefore, our net deferred tax assets are reduced by a valuation allowance to the extent that realization of the related deferred tax asset is not assured. We have recorded a valuation allowance for the full amount of our calculated deferred tax asset as of December 31, 2005 and 2004.

*Basic and Diluted Net Loss Per Common Share*

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. The computation of basic net loss per share for all periods presented is derived from the information on the face of the statement of operations, and there are no reconciling items in either the numerator or denominator.

**AVIGEN, INC.**  
(a development stage company)

**NOTES TO FINANCIAL STATEMENTS — (Continued)**

Diluted net loss per common share is computed as though all potential common shares that are dilutive were outstanding during the year, using the treasury stock method for the purposes of calculating the weighted-average number of dilutive common shares outstanding during the period. Potential dilutive common shares consist of shares issuable upon exercise of stock options and warrants. Securities that potentially could have diluted basic earnings per common share, but were excluded from the diluted net loss per common share computation because their inclusion would have been anti-dilutive, were as follows:

	Year Ended December 31,		
	2005	2004	2003
Potential dilutive stock options outstanding .....	273,667	530,731	554,852
Outstanding securities excluded from the potential dilutive common shares calculation (1) .....	3,756,850	3,970,588	4,512,838

- (1) For purposes of computing the potential dilutive common shares, we have excluded outstanding stock options and warrants to purchase common stock whose exercise prices exceed the average of the closing sale prices of our common stock as reported on the NASDAQ National Market for the period.

*New Accounting Pronouncements*

In May 2005, the FASB issued FASB Statement No. 154, ("FAS 154"), "Accounting Changes and Error Corrections." FAS 154 establishes retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. FAS 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. FAS 154 becomes effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the adoption of FAS 154 to have a material impact on our financial position, cash flows or results of operations.

In December 2004, the FASB issued FASB Statement No. 123(R), ("FAS 123(R)"), "Share-Based Payment," which is a revision of FASB Statement No. 123 ("FAS 123"), "Accounting for Stock-Based Compensation." FAS 123(R) supercedes APB Opinion No. 25, (APB 25), "Accounting for Stock Issued to Employees," and amends FASB Statement No. 95, "Statement of Cash Flows." FAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values at the date of grant and to record that cost as compensation expense over the period during which the employee is required to perform service in exchange for the award (generally over the vesting period of the award). Excess tax benefits, as defined by FAS 123(R), will be recognized as an addition to common stock. In April 2005, the SEC adopted a new rule that amends the compliance dates for FAS 123(R). In accordance with the new rule, we are required to implement FAS 123(R) at the beginning of our fiscal year that begins January 1, 2006. The Commission's new rule does not change the accounting required by FAS 123(R); it changes only the dates of compliance.

In November 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, "Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards." The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool ("APIC pool") related to the tax effects of employee share-based compensation, and to determine the subsequent impact on the APIC pool and consolidated statements of cash flows of the tax effects of employee share-based compensation awards that are outstanding upon adoption of SFAS 123(R). An entity may make a one-time election to adopt the transition method described in this guidance and may take up to one year from the later of its initial adoption of SFAS 123(R) or the effective date of this guidance, which was November 11, 2005. We are in the process of determining whether to adopt the alternative transition method provided in FAS 123(R)-3 for calculating the tax effects of share-based compensation pursuant to SFAS 123(R).

**AVIGEN, INC.**  
(a development stage company)

**NOTES TO FINANCIAL STATEMENTS — (Continued)**

Effective January 1, 2006, we will adopt FAS 123(R) using the modified prospective transition method, which provides for certain changes to the method for valuing share-based compensation. The valuation provisions of FAS 123(R) apply to new awards and to awards that are outstanding at the effective date and subsequently modified or cancelled. Estimated compensation expense for awards outstanding at January 1, 2006 will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. In accordance with the modified prospective transition method, our statements of operations for periods prior to January 1, 2006 will not be restated to reflect the impact of FAS 123(R).

Our calculation of share-based compensation expense in future periods will be calculated using the Black-Scholes option valuation model and will include the portion of share-based payment awards that is ultimately expected to vest during the period and therefore will be adjusted to reflect estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro forma information required under SFAS 123 for the periods prior to 2006, we accounted for forfeitures as they occurred. For share awards granted after January 1, 2006, expenses will be amortized under the straight-line attribution method. For share awards granted prior to 2006, expenses are amortized under the straight-line single option method prescribed by SFAS 123. We expect that our adoption of FAS 123(R) in 2006 will have a material impact on our results of operations and net loss per share.

*Stock-Based Compensation*

Until FAS 123(R) becomes effective for Avigen on January 1, 2006, we choose to continue to account for stock options granted to our employees and directors in accordance with APB Opinion 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations. Under APB 25, when the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized.

The information regarding net loss and loss per common share as required by FAS 123 has been determined as if we had accounted for our employee stock options under the fair value method prescribed by FAS 123. The resulting effect on net loss and loss per common share pursuant to FAS 123 is not likely to be representative of the effects on net loss and loss per common share pursuant to FAS 123 in future years, because future years are likely to include additional grants and because of the variable impact of future years' vesting.

The following table illustrates the effect on our net loss and loss per common share if we had applied the fair value recognition provisions of FAS 123 to our stock-based employee compensation (in thousands, except for per share data):

	Year Ended December 31,		
	2005	2004	2003
Net loss — as reported .....	\$(14,696)	\$(23,923)	\$(25,774)
Add: Stock-based employee compensation included in reported net loss .....	—	220	28
Less: Total stock-based employee compensation expense determined under the fair-value-based method for all awards .....	(2,219)	(6,637)	(9,941)
Net loss — pro forma .....	<u>\$(16,915)</u>	<u>\$(30,340)</u>	<u>\$(35,687)</u>
Net loss per common share basic and diluted — as reported .....	<u>\$ (0.71)</u>	<u>\$ (1.17)</u>	<u>\$ (1.28)</u>
Net loss per common share basic and diluted — pro forma .....	<u>\$ (0.82)</u>	<u>\$ (1.49)</u>	<u>\$ (1.77)</u>

**AVIGEN, INC.**  
(a development stage company)

**NOTES TO FINANCIAL STATEMENTS — (Continued)**

For purposes of disclosure pursuant to FAS 123, as amended by FAS 148, the estimated fair value of our employee stock options is amortized to expense on a straight-line basis over the vesting period of the options, generally over four years. We use the Black-Scholes option valuation model to estimate the fair value of our options on the date of grant. Options that were granted during the years ended December 31, 2005, 2004 and 2003 were valued with the following weighted average assumptions:

	Year Ended December 31,		
	2005	2004	2003
Expected volatility .....	0.6670	0.8110	0.8343
Risk free interest rate .....	4.05%	3.43%	2.97%
Expected life of options in years .....	4.5	5	5
Expected dividend yield .....	—	—	—

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options and warrants that have no vesting restrictions and are fully transferable. In addition, option valuation models, including Black-Scholes, require the input of highly subjective assumptions, including the expected stock price volatility. Because our stock options and warrants are not traded, they have characteristics significantly different from those of traded options and warrants, and because changes in the subjective input assumptions can materially affect the fair value estimate, in our opinion, the existing option valuation models, including Black-Scholes, do not necessarily provide a reliable single measure of the fair value of our stock options and warrants.

Our employee stock options are granted at a price equal to the fair market value of our stock on the date of the grant. The weighted-average estimated fair values of stock options granted during the fiscal years ended December 31, 2005, 2004, and 2003 as calculated using the Black-Scholes option pricing model were \$1.80, \$2.63, and \$2.60, respectively.

For equity awards to non-employees, including lenders, lessors, and consultants, we also apply the Black-Scholes method to determine the fair value of such investments in accordance with FAS 123 and Emerging Issues Task Force Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods, or Services." The options and warrants granted to non-employees are re-measured as they vest and the resulting value is recognized as an expense against our net loss over the period during which the services are received or the term of the related financing.

**2. Cash, Available-for-Sale Securities and Restricted Investments**

The following is a summary of cash, restricted investments, and available-for-sale securities as of December 31, 2005 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash .....	\$11,510	\$ —	\$ —	\$11,510
Corporate debt securities .....	21,415	—	(197)	21,218
Federal agency obligations .....	26,013	—	(306)	25,707
Asset-backed and other securities .....	9,882	5	(24)	9,863
Treasury obligations .....	2,108	—	(18)	2,090
Total .....	\$70,928	\$ 5	\$(545)	\$70,388
Amounts reported as:				
Cash and cash equivalents .....	\$11,510	\$ —	\$ —	\$11,510
Restricted investments .....	10,428	—	—	10,428
Available for sale securities .....	48,990	5	(545)	48,450
Total .....	<u>\$70,928</u>	<u>\$ 5</u>	<u>\$(545)</u>	<u>\$70,388</u>

**AVIGEN, INC.**  
(a development stage company)

**NOTES TO FINANCIAL STATEMENTS — (Continued)**

The weighted average maturity of our investment portfolio at December 31, 2005 was 291 days, with \$37.7 million carrying an effective maturity of less than twelve months, and \$32.7 million carrying an effective maturity between one and three years.

The following is a summary of cash, restricted investments, and available-for-sale securities as of December 31, 2004 (in thousands):

	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Cash .....	\$ 3,217	\$ —	\$ —	\$ 3,217
Corporate debt securities .....	33,438	1	(210)	33,229
Federal agency obligations .....	27,362	—	(248)	27,114
Asset-backed and other securities .....	3,200	—	(34)	3,166
Auction rate certificates .....	3,350	—	—	3,350
Treasury obligations .....	6,176	—	(34)	6,142
<b>Total .....</b>	<b>\$76,743</b>	<b>\$ 1</b>	<b>\$(526)</b>	<b>\$76,218</b>
Amounts reported as:				
Cash and cash equivalents .....	\$ 3,217	\$ —	\$ —	\$ 3,217
Restricted investments .....	11,928	—	—	11,928
Available-for-sale securities .....	61,598	1	(526)	61,073
<b>Total .....</b>	<b>\$76,743</b>	<b>\$ 1</b>	<b>\$(526)</b>	<b>\$76,218</b>

The weighted average maturity of our investment portfolio at December 31, 2004 was 354 days, with \$42.7 million carrying an effective maturity of less than twelve months, and \$33.5 million carrying an effective maturity between one and three years.

Net realized loss was approximately \$32,000 for the year ended December 31, 2005, and net realized gains were \$119,000, and \$444,000 for the years ended December 31, 2004 and 2003, respectively.

At December 31, 2005 and 2004, we had the following available-for-sale securities that were in a continuous unrealized loss position but were not deemed to be other-than-temporarily impaired (in thousands):

	<u>Less Than 12 Months</u>		<u>12 Months or Greater</u>	
	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
<b>December 31, 2005</b>				
Corporate debt securities .....	\$(108)	\$11,246	\$ (88)	\$ 8,883
Federal agency obligations .....	(101)	12,789	(205)	12,918
Asset-backed and other securities .....	(4)	996	(20)	5,385
Treasury obligations .....	(8)	1,201	(11)	889
<b>Total .....</b>	<b>\$(221)</b>	<b>\$26,232</b>	<b>\$(324)</b>	<b>\$28,075</b>
	<u>Less Than 12 Months</u>		<u>12 Months or Greater</u>	
	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
<b>December 31, 2004</b>				
Corporate debt securities .....	\$ (96)	\$18,844	\$(114)	\$13,532
Federal agency obligations .....	(50)	8,434	(199)	18,680
Asset-backed and other securities .....	(34)	2,885	—	—
Treasury obligations .....	(25)	4,848	(8)	1,294
<b>Total .....</b>	<b>\$(205)</b>	<b>\$35,011</b>	<b>\$(321)</b>	<b>\$33,506</b>

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**NOTES TO FINANCIAL STATEMENTS — (Continued)**

The gross unrealized losses reported above for 2005 and 2004 were caused by rises in market interest rates during those periods. No significant facts or circumstances have occurred to indicate that these unrealized losses are related to any deterioration in the creditworthiness of the issuers of the marketable securities we own. Based on our review of these securities, including our assessment of the duration and severity of the related unrealized losses, we have not recorded any other-than-temporary impairments on these investments.

**3. Property and Equipment**

Property and equipment consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2005</u>	<u>2004</u>
Leasehold improvements .....	\$ 6,742	\$ 18,439
Laboratory equipment .....	1,551	6,930
Office furniture and equipment .....	1,702	2,301
	9,995	27,670
Less accumulated depreciation and amortization .....	(6,066)	(15,173)
Property and equipment, net .....	<u>\$ 3,929</u>	<u>\$ 12,497</u>

Total depreciation and amortization expense for the years ended December 31, 2005, 2004 and 2003, was \$2.5 million, \$3.6 million, and \$3.6 million, respectively. For the year ended December 31, 2005, the decreases in the balances of leasehold improvements, laboratory equipment, and office furniture and equipment reflect reductions in our cost basis for these long-lived assets due to impairment charges recorded during the year of \$11.7 million, \$5.4 million, and \$260,000, respectively. Similarly, for the year ended December 31, 2005, accumulated depreciation was reduced by \$11.2 million, primarily in connection with the recognition of the impairment charges.

**4. Impairment Loss related to Long-Lived Assets:**

During 2005, we took steps to discontinue funding of our AAV-based programs in order to focus our development efforts and financial resources on our non-gene therapy product candidates. As a result, we determined that our future operations would not require the full capacity of our currently leased facilities. Therefore, at June 30, 2005, we evaluated the ongoing value of the leasehold improvements and equipment associated with approximately 40,000 square feet of manufacturing, laboratory, and office space, which we have under lease through July 2008. In September 2005, we took additional steps to consolidate our operations in order to sublease additional portions of our leased facilities. As a result, at September 30, 2005, we evaluated the ongoing value of the leasehold improvements associated with 11,000 square feet of manufacturing, laboratory, and office space we have under lease through November 2010.

Based on these evaluations, we determined that long-lived assets with a net carrying value of \$6.1 million were no longer recoverable and were in fact impaired. For the year ended December 31, 2005, we recorded an impairment loss related to long-lived assets in the facilities and wrote down the related carrying value of the leasehold improvements, laboratory and office equipment and furniture to approximate their estimated fair value.

Fair value was based on the expected incremental sublease cash flows we estimated we could receive in excess of our prorated existing operating lease obligations based on current market lease rental rates at the time for similar mixed use properties. Based on current market conditions, including vacancy rates and the expected time needed to sublease the facilities, we did not expect to receive significant incremental rents related to the long-lived assets. The impairment charges primarily represent accelerated depreciation expense, which is a non-cash expense that was scheduled to be recognized over the next five years.

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**NOTES TO FINANCIAL STATEMENTS — (Continued)**

**5. Termination Costs Associated with Exit Activities**

In August 2005, we took steps to reduce our research and development spending attributable to gene therapy activities. As a result, we reduced the level of our total staff by approximately 19 positions, primarily in research and development. This action qualified as an exit activity under FAS 146, "Costs Associated with Exit or Disposal Activities." In connection with this reduction in staff, we incurred approximately \$646,000 in severance and other termination-related benefits. Approximately \$624,000 of the costs associated with the workforce reduction are included in research and development expenses and approximately \$22,000 are included in general and administrative expenses for year ended December 31, 2005. At December 31, 2005, approximately \$25,000 was unpaid and included on our balance sheet under accrued compensation and related expenses. These accrued amounts primarily represent deferred severance payments and extended health care benefits for certain impacted employees. We do not expect to incur any additional costs associated with the workforce reduction.

**6. Collaboration Agreement — Bayer Corporation**

In March 2003, we received a \$2.5 million payment from Bayer Corporation under the terms of a collaboration agreement for the development of an AAV-based gene therapy product for hemophilia. This amount was recorded as deferred revenue and was being recognized as revenue ratably at approximately \$125,000 per quarter over the estimated development period for this product, which was determined to be five years. In May 2004, we suspended subject enrollment in the phase I clinical trial, which resulted in the termination of the development of the product candidate associated with the Bayer payment. As a result, we accelerated the recognition of the remaining \$2.0 million of deferred revenue in our statements of operations during the year ended December 31, 2004.

**7. AAV Gene Therapy Assignment Agreement — Genzyme Corporation**

In December 2005, we entered into an agreement with Genzyme Corporation which included the assignment of certain of our intellectual property to previously developed gene therapy technologies, rights to our gene therapy clinical trial programs for Parkinson's disease and hemophilia, and certain clinical-grade materials, subject to the potential reversion to us of specified rights under specified conditions. Under the terms of the agreement, we received a \$12 million initial payment and could receive significant additional development-based milestone, sublicensing fees and royalty payments. The initial payment was non-refundable and as of December 31, 2005, and Avigen did not have any significant performance obligations associated with the agreement. Because we could receive significant future cash flows in connection with this agreement, if Genzyme is successful in developing products using patents included in the agreement, we have not accounted for this transaction as discontinued operations. As such, we recognized the entire initial payment as revenue in 2005 and expect that any future payments we receive under the terms of the agreement will also be recorded as revenue.

**8. Loan Payable**

In June 2000, we entered into a financing arrangement to support construction related activities. Under this arrangement, we had the right to borrow up to \$10.0 million through June 1, 2003. This revolving line of credit was amended in June 2002 to extend the expiration date to June 1, 2005, and amended again in June 2004 to extend the expiration date to June 1, 2007. Accordingly, the loan continues to be classified as long term. Amounts borrowed under this arrangement bear interest at the London Inter-Bank Offered Rate plus a margin adjustment that varies between 0.5% and 1.0% on the date of each drawdown based on the market value of our investment portfolio held with a subsidiary of Wells Fargo. This interest rate is subsequently reset every three months. The weighted average interest rate for all outstanding drawdowns on this long-term obligation was 4.97% and 2.70% at December 31, 2005 and 2004, respectively. We have pledged a portion of our portfolio of available-for-sale securities equal to the amount of outstanding borrowings to secure this long-term obligation, and have identified these pledged assets as restricted investments on our balance sheets. As of both December 31, 2005 and 2004, we had borrowed \$8.0 million from the line of credit. Payments of interest only are due monthly through June 1, 2007, at which time a balloon payment of outstanding principal is due. In November 2000, we reserved \$2.0 million in borrowing

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**NOTES TO FINANCIAL STATEMENTS — (Continued)**

capacity from the line of credit to secure a letter of credit. The letter of credit was established pursuant to the terms required under a ten-year property lease entered into in November 2000, and was issued in favor of the property owner. As a result of the cash borrowings and the establishment of the letter of credit, we did not have any remaining borrowing capacity under the line of credit at December 31, 2005.

**9. Stockholders' Equity**

*Common Stock*

In August and September 1998, we issued an aggregate of 1,306,505 shares of our common stock at \$2.25 to \$2.94 per share to selected institutional investors. The offering was completed through a private placement. As part of the transaction, we issued warrants to purchase 261,301 shares of our common stock with an exercise price of \$2.18 to \$3.67 per share. The exercise price was 125% of the fair market value per share of our underlying stock on the corresponding closing day and the warrants carry a five-year term. After deducting commissions and fees from the gross proceeds of \$2,969,000, net proceeds from this transaction approximated \$2,735,000.

In December 1998, we issued 1,367,280 shares of our common stock at \$3.81 to \$4.88 per share to selected institutional investors. The offering was completed through a private placement. As part of this transaction, we issued warrants to purchase 273,456 shares of our common stock with an exercise price ranging from \$4.76 to \$6.09 per share. The exercise price was 125% of the fair market value per share of our underlying stock on the corresponding closing day and the warrants carry a five-year term. After deducting commissions and fees from the gross proceeds of \$5,635,000, net proceeds from this transaction approximated \$5,197,000.

In February and April 1999, we issued an aggregate of 2,198,210 shares of our common stock at \$5.50 to \$6.00 per share to selected institutional investors. The offering was completed through a private placement. As part of this transaction, we issued warrants to purchase 439,642 shares of our common stock with an exercise price of \$6.87 to \$7.50 per share. The exercise price was 125% of the fair market value per share of the underlying stock on the corresponding closing day and the warrants carry a five-year term. After deducting commissions and fees from the gross proceeds of \$13,189,000, net proceeds from this transaction approximated \$12,156,000.

In October and November 1999, we issued an aggregate of 2,033,895 shares of our common stock at \$16.19 to \$25.56 per share to selected institutional investors. The offering was completed through a private placement. As part of this transaction, we issued warrants to purchase 406,779 shares of our common stock with an exercise price of \$20.25 to \$31.95 per share. The exercise price was 125% of the fair market value per share of our underlying stock on the corresponding closing day and the warrants carry a five-year term. After deducting commissions and fees from the gross proceeds of \$40,028,000, net proceeds from this transaction approximated \$37,222,000.

In March 2000, we issued a warrant to purchase 40,000 shares of our common stock as partial consideration for the extension of our building lease. The fair value of this warrant at the date of issuance was approximately \$1,738,000. This fair value is being amortized over the life of the lease extension, or May 2008. This warrant was issued with an exercise price equal to the fair market value per share of our underlying stock at the time of issuance, or \$56.00, and carried a five-year term. In March 2005, this warrant expired unexercised.

Also, in March 2000, we issued a warrant to purchase 50,000 shares of our common stock as partial consideration for the acquisition of certain patent licenses previously used in our gene therapy-related research and development activities. The fair value of this warrant at the date of issuance was approximately \$3,182,000 and was fully expensed in the year ended June 30, 2000. This warrant was issued with an exercise price equal to the fair market value per share of our underlying stock at the time of issuance, or \$82.00, and carried a five-year term. In March 2005, this warrant expired unexercised.

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**NOTES TO FINANCIAL STATEMENTS — (Continued)**

In April and May 2000, we issued an aggregate of 1,150,000 shares of our common stock at \$26.00 per share through a public offering. After deducting commissions and fees from the gross proceeds of \$29,900,000, net proceeds from this transaction totaled \$27,611,000.

In November 2000, we issued an aggregate of 2,291,239 shares of our common stock between \$37.50 and \$45.06 per share through a public offering. After deducting combined commissions and fees from the gross proceeds of \$90,706,000, net proceeds from this transaction totaled \$86,086,000.

In February 2001, we issued 313,636 shares of common stock at \$47.82 per share to Bayer AG, in connection with a collaboration agreement entered into with Bayer Corporation dated November 17, 2000. Net proceeds from this transaction totaled \$15,000,000.

In March 2004, we issued a warrant to purchase 15,000 shares of our common stock as partial consideration for the acquisition of certain intellectual property rights used in our research and development activities. The fair value of this warrant was approximately \$97,000 when we entered into the corresponding license agreement in October 2003. The fair value of the warrant was fully expensed and recorded in accounts payable and other accrued liabilities as of December 31, 2003. Upon issuance, the fair value of the warrant was reclassified to additional paid in capital for the year ended December 31, 2004. This warrant was issued with an exercise price equal to the fair market value per share of our underlying stock at the time of issuance, or \$6.50, and carries a ten-year term. At December 31, 2005, this was the only issued warrant Avigen had that was outstanding.

During the year ended December 31, 2005, we received \$286,000 in cash proceeds related to the exercise of stock options for 526,023 shares of common stock.

*Shares Reserved for Future Issuance*

We have reserved shares of our common stock for future issuance as follows:

	<u>December 31,</u> <u>2005</u>
Stock options outstanding .....	3,487,254
Stock options available for grant .....	4,798,546
Warrants to purchase common stock .....	15,000
Shares available for Employee Stock Purchase Plan ....	<u>360,000</u>
	<u>8,660,800</u>

**10. Stock Options and Stock Purchase Plan**

*Employee Stock Option Plans*

Under the 1993 Stock Option Plan (the "1993 Plan"), prior to March 1996, incentive and nonqualified stock options could be granted to our key employees, directors and consultants to purchase up to 1,500,000 shares of common stock. Under the 1993 Plan, options could be granted at a price per share not less than the fair market value at the date of grant. In March 1996, the Board determined to grant no further options under the 1993 Plan and adopted the 1996 Equity Incentive Plan. At December 31, 2005, there were options to purchase 24,458 shares outstanding under the 1993 Plan, with no further shares available for grant. These options were scheduled to expire in February 2006.

The 1996 Equity Incentive Plan ("1996 Plan") provides for grants of incentive and nonqualified stock options, restricted stock purchase awards, stock bonuses and stock appreciation rights to our employees, directors and consultants. The Plan originally authorized the grant of options to purchase up to 600,000 shares of common stock. As a result of a series of amendments which were approved by stockholders, prior to December 31, 2005, there

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**NOTES TO FINANCIAL STATEMENTS — (Continued)**

were 3,500,000 shares authorized for grant under the 1996 Plan. Under the 1996 Plan, incentive stock options may be granted at a price per share not less than the fair market value at the date of grant, and nonqualified stock options may be granted at a price per share not less than 85% of the fair market value at the date of grant. Options granted generally have a maximum term of 10 years from the grant date and become exercisable over four years. At December 31, 2005, there were options to purchase 1,213,161 shares outstanding under the 1996 Plan and 1,537,137 shares available for grant. This Plan is scheduled to expire in March 2006. At that time, the Plan would no longer have any options available for future grant.

In June 2000, the Board of Directors adopted the 2000 Equity Incentive Plan ("2000 Plan") which provides for grants of nonqualified stock options, restricted stock purchase awards, and stock bonuses to our employees, directors and consultants to purchase up to 5,000,000 shares of common stock; provided, however, that generally only up to 40% of the shares subject to grants under the 2000 Plan may be made to our directors and officers. Under the 2000 Plan, options may be granted at a price per share not less than 85% of the fair market value at the date of grant. Options granted generally have a maximum term of 10 years from the grant date and become exercisable over four years. At December 31, 2005, there were options to purchase 1,967,252 shares outstanding under the 2000 Plan and 3,018,792 shares available for grant.

*Employee Stock Purchase Plan*

In September 1997, we adopted the 1997 Employee Stock Purchase Plan ("Purchase Plan"). A total of 360,000 shares of our common stock have been reserved for issuance under the Purchase Plan. As of December 31, 2005, there have been no employee contributions to the Purchase Plan.

*Non-employee Stock Options*

In July 1995, we granted the Chairman of our Board of Directors an option to purchase 515,248 shares of our common stock at \$0.49 per share, exercisable for 10 years from the date of grant. Such grant was made outside of any of our stock option plans. In July 2005, the option was fully exercised and was no longer outstanding.

The 1996 Non-Employee Directors' Stock Option Plan (the "Directors' Plan") provides for automatic grants of options to purchase shares of our common stock to our non-employee directors. The Plan originally authorized the grant of options to purchase up to 200,000 shares of common stock. As a result of a series of amendments which were approved by stockholders, prior to December 31, 2005, there were 550,000 shares authorized for grant under the Director's Plan at December 31, 2005. As of December 31, 2005, nonqualified options to purchase approximately 327,383 shares of common stock between \$2.00 and \$40.75 per share, exercisable for 10 years from the date of grant, have been granted under the Directors' Plan, of which options to purchase 282,383 shares remained outstanding. At December 31, 2005, there were 242,617 shares available for grant under the Directors' Plan. This Plan is scheduled to expire in March 2006. At that time, the Plan would no longer have any options available for future grant.

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**NOTES TO FINANCIAL STATEMENTS — (Continued)**

The following table summarizes option activity with regard to all stock options:

	Outstanding Options	
	Number of Shares	Weighted-Average Exercise Price per Share
Outstanding at December 31, 2002 .....	<u>4,144,488</u>	<u>14.31</u>
Granted .....	685,800	3.73
Canceled .....	(404,100)	16.21
Exercised .....	<u>(63,746)</u>	<u>3.81</u>
Outstanding at December 31, 2003 .....	<u>4,362,442</u>	<u>12.62</u>
Granted .....	1,111,150	3.92
Canceled .....	(962,008)	14.63
Exercised .....	<u>(86,856)</u>	<u>4.63</u>
Outstanding at December 31, 2004 .....	<u>4,424,728</u>	<u>10.16</u>
Granted .....	658,366	3.17
Canceled .....	(1,069,817)	8.25
Exercised .....	<u>(526,023)</u>	<u>0.54</u>
Outstanding at December 31, 2005 .....	<u>3,487,254</u>	<u>10.87</u>

The following table summarizes information with regard to total stock options outstanding under all stock option plans at December 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Of Shares	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Of Shares	Weighted-Average Exercise Price
\$ 0.71 – \$ 3.13 .....	469,633	8.09	\$ 2.85	147,916	\$ 2.59
3.14 – 3.31 .....	180,929	7.96	\$ 3.20	51,737	\$ 3.26
3.38 – 3.38 .....	365,625	8.48	\$ 3.38	124,999	\$ 3.38
3.45 – 3.53 .....	458,362	7.42	\$ 3.50	199,813	\$ 3.52
3.63 – 6.00 .....	362,950	4.29	\$ 4.93	302,286	\$ 5.04
6.16 – 8.53 .....	459,249	6.60	\$ 7.42	310,577	\$ 7.70
8.88 – 14.36 .....	124,374	5.92	\$10.77	123,492	\$10.77
14.63 – 14.63 .....	496,632	4.22	\$14.63	496,632	\$14.63
15.44 – 38.19 .....	527,000	3.74	\$33.20	527,000	\$33.20
40.75 – 47.63 .....	<u>42,500</u>	<u>4.51</u>	<u>\$43.99</u>	<u>42,500</u>	<u>\$43.99</u>
\$ 0.71 – \$47.63 .....	<u>3,487,254</u>	<u>6.12</u>	<u>\$10.87</u>	<u>2,326,952</u>	<u>\$14.42</u>

The numbers of options exercisable at December 31, 2004 and 2003 were 2,720,885 and 2,787,690, respectively, with a weighted average exercise price of \$13.32 and \$14.28, respectively.

In August 2005, in connection with the resignation of an executive, we modified the expiration terms for options representing 107,500 shares of common stock, but did not extend the maximum contractual term. At the time of this modification, there was no intrinsic value as the exercise price for these stock options exceeded the market price. As a result, we did not record any compensation expense in connection with the modification. At December 31, 2005, these options expired unexercised.

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**NOTES TO FINANCIAL STATEMENTS — (Continued)**

In March 2004, in connection with the resignation of an executive, we modified the vesting and expiration terms for options representing 473,000 shares of common stock, but did not extend the maximum contractual term. These modifications resulted in the recognition of \$220,000 in non-cash compensation expense during 2004.

In February 2003, in connection with the resignation of two executives, we modified the vesting and expiration terms for options representing 276,872 shares of common stock, but did not extend the maximum contractual term. These modifications resulted in the recognition of \$23,000 in non-cash compensation expense during 2003.

**11. Employee Profit Sharing/401(k) Plan**

In January 1996, we adopted a Tax Deferred Savings Plan under Section 401(k) of the Internal Revenue Code (the "Plan") for all full-time employees. Under the Plan, our eligible employees can contribute amounts to the Plan via payroll withholding, subject to certain limitations. Our matching contributions to the Plan are discretionary and can only be made in cash. Effective July 1, 2001, we began matching 25% of an employee's contributions up to \$2,500 per Plan year. These matching contributions vest ratably over a five-year period based on the employee's initial hire date. Our matching contributions for all employees for the years ended December 31, 2005, 2004 and 2003 were approximately \$76,000, \$100,000 and \$112,000, respectively.

**12. Commitments and Sublease Accounting**

We lease an aggregate of 112,000 square feet of laboratory, manufacturing, and office facilities from two adjacent buildings in Alameda, California under two non-cancelable operating lease agreements which expire in May 2008 and November 2010. Our lease for 45,000 square feet from one building which expires in May 2008, contains an extension option for five years under the same terms and conditions as the original lease agreement. As security for performance of future obligations under these leases, we have pledged \$2.4 million of our available-for-sale securities to secure letters of credit that serve as deposits. These amounts are classified as restricted investments in our balance sheets.

As of December 31, 2005, approximately 26,250 square feet of our aggregate facilities is subleased to two separate corporate tenants not affiliated with Avigen. The sublease agreements run concurrent with the respective duration of our underlying lease term on each building.

At December 31, 2005, our future minimum commitments under non-cancelable facilities operating leases, net of sublease income, are as follows (in thousands):

	<u>Minimum Lease Commitments</u>	<u>Sublease Income</u>	<u>Net Lease Commitments</u>
Year ending December 31:			
2006 .....	\$ 2,437	\$ (532)	\$1,905
2007 .....	2,543	(574)	1,969
2008 .....	2,007	(392)	1,615
2009 .....	1,624	(252)	1,372
2010 and thereafter .....	1,542	(239)	1,303
Total .....	<u>\$10,153</u>	<u>\$(1,989)</u>	<u>\$8,164</u>

Expenses and income associated with operating leases and subleases were as follows (in millions):

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Rent Expense .....	\$ 2.6	\$2.6	\$2.4
Sublease income, net .....	(0.1)	—	—

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**NOTES TO FINANCIAL STATEMENTS — (Continued)**

In 2005, we recorded an investment in deferred financing leases of approximately \$220,000 and recorded unearned income of approximately \$155,000. This deferred financing lease was related to equipment sold to one of our subtenants and carries a term equal to the related sublease agreement, or 30 months. Unearned income will be recognized ratably over the term of the lease, or approximately \$5,200 per month.

In the ordinary course of business, we enter into commitments to fund collaborative research and clinical work performed by third parties. While these contracts are cancelable, we expect the research studies and clinical work to be completed as defined in the terms of the agreements, and all amounts paid when due. At December 31, 2005, the estimated costs related to these commitments totaled approximately \$510,000, all of which is expected to be paid within the next twelve to twenty-four months.

*Sublease Accounting*

We have entered into sublease agreements for portions of our leased laboratory and office facilities. Based on the terms of the agreements, the fair value of our remaining lease liability is less than the scheduled sublease income. As a result, in the period ended December 31, 2005, we did not record any lease exit costs associated with the sublease of our operating facilities located at 1201 and 1301 Harbor Bay Parkway. In connection with the sublease agreements, we recorded initial direct costs of \$114,000 in commission expenses. We amortize initial direct costs to operating expenses on a straight-line basis over the term of the sublease.

**13. Income Taxes**

Significant components of our deferred tax assets are as follows (in thousands):

	December 31,	
	2005	2004
Net operating loss carryforward .....	\$ 56,000	\$ 52,500
Research and development credits .....	7,600	7,400
Capitalized research and development .....	7,100	6,500
Depreciation .....	3,200	2,700
Capitalized patents .....	500	800
Other .....	3,300	1,000
Gross deferred tax assets .....	77,700	70,900
Valuation allowance .....	(77,700)	(70,900)
Net deferred tax assets .....	<u>\$ —</u>	<u>\$ —</u>

No provision has been made for income taxes because we have incurred losses since our inception. Deferred income taxes reflect the net tax effects of temporary differences between the carrying value of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

We have increased our valuation allowance by \$6.8 million, \$10.0 million and \$11.0 million in 2005, 2004 and 2003, respectively, to provide a full valuation allowance for deferred tax assets since the realization of these benefits is not considered more likely than not.

At December 31, 2005, we had unused net operating loss carryforwards of \$159.0 million available to reduce federal taxable income expiring on various dates from 2008 through 2025 and \$33.0 million available to reduce state taxable income expiring on various dates from 2006 through 2015. We also have federal and state research tax credits of \$5.2 million and \$3.7 million, respectively, available to offset federal and state income taxes, which expire on various dates from 2012 through 2025. Deferred tax assets related to carryforwards at December 31, 2005 include approximately \$2.0 million associated with stock option activity for which any subsequently recognized benefits will be credited directly to stockholders' equity. Our net operating losses and tax credit

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**NOTES TO FINANCIAL STATEMENTS — (Continued)**

carryforwards may be subject to the annual limitation provisions of Internal Revenue Code (IRC) Sections 382 and 383 if we incur a "change in ownership."

**14. Condensed Quarterly Financial Information (Unaudited)**

	Year Ended December 31, 2005			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
(amounts in thousands except per share data)				
Total revenue .....	\$ 9	\$ 11	\$ 4	\$12,002
Net loss .....	(5,190)	(9,848)	(6,764)	7,106
Net loss per share, basic and diluted .....	(0.25)	(0.48)	(0.32)	0.34
	Year Ended December 31, 2004			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
(amounts in thousands except per share data)				
Total revenue .....	\$ 150	\$ 2,002	\$ 8	\$ 35
Net loss .....	(7,281)	(4,513)	(6,470)	(5,659)
Net loss per share, basic and diluted .....	(0.36)	(0.22)	(0.32)	(0.27)

**15. Subsequent Event — Sanochemia-License Agreement**

In January 2006, we entered into a license agreement with SDI Diagnostics International LTD, a division of Sanochemia Pharmazeutika AG (Sanochemia). Under the terms of the agreement, Avigen received an exclusive license to develop and commercialize the compound tolperisone in North America. This compound is the active pharmaceutical ingredient in our product candidate, AV650, for the treatment of neuromuscular spasm and spasticity. Under the terms of the agreement, Avigen paid Sanochemia \$3.0 million in initial license costs and will make additional future payments based on successful clinical and regulatory product development milestones and royalty payments on sales. The companies have also entered into a long-term supply agreement under which Sanochemia will manufacture the AV650 product for Avigen. We will also owe payments for clinical and commercial supply.

**16. Subsequent Event — Severance**

In January 2006, our Chief Financial Officer resigned from the Company. In connection with his resignation, Avigen has agreed to pay severance benefits including base salary for a period of one year and continued health benefits for up to twelve months. As a result of this separation, we expect to report a charge in the quarter ending March 31, 2006 of approximately \$290,000. In addition, Avigen agreed to modify outstanding stock options held by the executive to allow for six months of additional vesting and an extended period to exercise all vested stock options for up to two years. As a result of this modification, we expect to report a charge for non-cash compensation expense for the quarter ending March 31, 2006.

**Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

**Item 9A. *Controls and Procedures***

***Evaluation of disclosure controls and procedures.*** With the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, Rules 13a-15(e) and 15(d)-15(e)), as of December 31, 2005. Based on that evaluation, the principal executive officer and principal financial officer have concluded that these disclosure controls and procedures were effective to ensure, at a reasonable assurance level, that the information required to be disclosed by us in reports we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and instructions for such reports.

***Management's Report on Internal Control over Financial Reporting.*** Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework*. Our management has concluded that, as of December 31, 2005, our internal control over financial reporting was effective based on these criteria.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by Ernst & Young LLP, the independent registered public accounting firm that audited our financial statements included in this Annual Report on Form 10-K, as stated in their report, a copy of which is included on the next page.

***Changes in Internal Control over Financial Reporting.*** There were no changes in our internal control over financial reporting during the quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Avigen Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Controls over Financial Reporting, that Avigen, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Avigen Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Avigen, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Avigen, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Avigen, Inc. as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005 and the period from inception (October 22, 1992) through December 31, 2005 of Avigen, Inc. and our report dated March 14, 2006 expressed an unqualified opinion thereon.

Palo Alto, California  
March 14, 2006

**Item 9B. Other Information**

On December 19, 2005, Avigen, Inc. entered into an agreement under which Genzyme Corporation would acquire Avigen's non-pain related AAV gene therapy assets. Under the terms of the agreement, Avigen sold the rights to its extensive patent estate based on adeno-associated virus technologies, rights to its clinical development program for Parkinson's disease, which includes the related phase I/II clinical trial currently underway at University of California, San Francisco, and the rights to a clinical collaboration in hemophilia with Dr. Katharine High of the University of Pennsylvania School of Medicine.

Avigen received an upfront payment from Genzyme of \$12.0 million and will receive additional milestone and royalty payments and license fees based on the development, approval and sale of all products developed by Genzyme that rely on intellectual property purchased from Avigen. However, if Genzyme fails to diligently pursue the commercialization or marketing of products using the assigned technology, as specified in the agreement, certain of the rights Avigen assigned could revert back to Avigen at a future date. The agreement is filed as Exhibit 10.58 to this Annual Report on Form 10-K.

The \$12.0 million received from Genzyme was booked as revenue for the quarter ending December 31, 2005, and increased Avigen's cash at December 31, 2005 by \$12.0 million and correspondingly decreased its deficit accumulated during the development stage by \$12.0 million. Other than these items, the transaction has no other impact on Avigen's balance sheet as of December 31, 2005 or statement of operations for the quarter or year ended December 31, 2005.

**PART III****Item 10. Directors and Executive Officers of the Registrant**

The information required by this Item with respect to Executive Officers may be found under the caption, "Executive Officers of the Registrant" at the end of Part I of this Annual Report on Form 10-K. The information required by this Item with respect to Directors, including information with respect to audit committee financial experts, is incorporated herein by reference from the information under the caption, "Proposal 1 — Election of Directors" appearing in the definitive Proxy Statement to be delivered to Avigen's stockholders in connection with the solicitation of proxies for Avigen's 2006 Annual Meeting of Stockholders to be held on May 31, 2006 (the "Proxy Statement").

***Section 16(a) Beneficial Ownership Reporting Compliance***

The information required by this Item with respect to compliance with Section 16(a) of the Exchange Act is incorporated herein by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Proxy Statement.

***Code of Business Conduct and Ethics***

The information required by this Item with respect to our code of ethics is incorporated herein by reference from the section captioned "Proposal 1 — Election of Directors — Code of Business Conduct and Ethics" contained in the Proxy Statement.

**Item 11. Executive Compensation**

The information required by this Item is set forth in the Proxy Statement under the captions, "Executive Compensation" and "Compensation Committee Interlocks and Insider Participation." Such information is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this Item with respect to security ownership of certain beneficial owners and management is set forth in the Proxy Statement under the caption, "Security Ownership of Certain Beneficial Owners and Management." Such information is incorporated herein by reference.

The information required by this Item with respect to securities authorized for issuance under our equity compensation plans is set forth in the Proxy Statement under the caption "Proposal 2 — Approval of the Avigen.

Inc. 2006 Equity Incentive Plan — Equity Compensation Plan Information”. Such information is incorporated herein by reference.

**Item 13. *Certain Relationships and Related Transactions***

The information required by this Item is set forth in the Proxy Statement under the heading “Certain Relationships and Related Transactions.” Such information is incorporated herein by reference.

**Item 14. *Principal Accountant Fees and Services***

The information required by this Item is set forth in the Proxy Statement under the heading “Proposal 3 — Ratification of Selection of Independent Registered Public Accounting Firm.” Such information is incorporated herein by reference.

Consistent with Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002, we are responsible for listing the non-audit services approved by our Audit Committee to be performed by Ernst & Young LLP, our external auditor. Non-audit services are defined as services other than those provided in connection with an audit or a review of our financial statements. The Audit Committee has not approved, and Ernst & Young LLP has not provided, any non-audit services other than those that Avigen has disclosed in previous SEC filings.

**PART IV**

**Item 15. *Exhibits and Financial Statement Schedules***

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) ***Financial Statements:***

Report of Independent Registered Public Accounting Firm  
Balance Sheets  
Statements of Operations  
Statements of Stockholders' Equity  
Statements of Cash Flows  
Notes to Financial Statements

(2) ***Financial Statement Schedules***

Financial statement schedules have been omitted from this Annual Report on Form 10-K because they are either not applicable or the required information is provided in the financial statements or the notes thereto.

(3) *Exhibits*

<u>Exhibit Number</u>	<u>Exhibits</u>
2.1	See Exhibit 10.58
3.1(1)	Amended and Restated Certificate of Incorporation
3.1.1(13)	Certificate of Amendment to Certificate of Incorporation
3.2 (1)	Restated Bylaws of the Registrant
4.1(1)	Specimen Common Stock Certificate
10.2(1, 2)	1993 Stock Option Plan
10.3 (2, 17)	1996 Equity Incentive Plan, as amended
10.4(1, 2)	Form of Incentive Stock Option Grant for 1996 Equity Incentive Plan
10.5(1, 2)	Form of Nonstatutory Stock Option Grant for 1996 Equity Incentive Plan
10.6(2, 14)	1996 Non-Employee Directors' Stock Option Plan, as amended
10.7(2, 4)	1997 Employee Stock Purchase Plan
10.8(1, 2)	Form of Indemnification Agreement between Avigen and its directors and executive officers.
10.10(2, 5)	2000 Equity Incentive Plan
10.11(2, 12)	Form of Nonstatutory Stock Option Grant for 2000 Equity Incentive Plan
10.14(2, 15)	Form of Incentive Stock Option Grant for 1993 Stock Option Plan
10.15(2, 15)	Form of Nonstatutory Stock Option Grant for 1993 Stock Option Plan
10.16(2, 24)	Form of Nonstatutory Stock Option Grant for 1996 Non-Employee Directors' Stock Option Plan, as amended
10.17(2, 25)	Compensation Agreements with Named Executive Officers
10.29(2, 6)	Employment Agreement dated August 14, 1996, between Avigen and Thomas J. Paulson.
10.32(15)	Revolving line of credit note signed November 2, 2000 with Wells Fargo Bank.
10.33(15)	Letter Agreement to the revolving line of credit note signed November 2, 2000 with Wells Fargo Bank.
10.36(2, 8)	Management Transition Plan
10.41(10)	Property Lease Agreement between ARE-1201 Harbor Bay, LLC and Avigen, dated February 29, 2000
10.45(13)	Office Lease Agreement between Lincoln-RECP Empire OPCO, LLC and Avigen, Inc., dated November 2, 2000.
10.46(13)	First Amendment to Lease Agreement between Lincoln-RECP Empire OPCO, LLC and Avigen, Inc., dated December 1, 2000.
10.47(13)	Second Amendment to Lease Agreement between Lincoln-RECP Empire OPCO, LLC and Avigen, Inc., dated February 12, 2001.
10.49(16)	Revolving line of credit note with Wells Fargo Bank, dated June 1, 2002.
10.50(16)	Letter of Agreement to the revolving line of credit note signed June 1, 2002 with Wells Fargo Bank.
10.51(11, 23)	License Agreement, dated November 21, 2003, by and between University of Colorado and Avigen

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10.53 (20)	Revolving line of credit note with Wells Fargo Bank, dated June 1, 2004
10.54 (20)	Amendment to Letter of Agreement to the revolving line of credit note signed June 1, 2004 with Wells Fargo Bank
10.55 (2, 21)	Arrangement Regarding Non-Employee Director Compensation
10.56 (26)	Sublease Lease Agreement, dated November 4, 2005, between Pepgen Corporation and Avigen
10.57 (27)	Sublease Lease Agreement, dated November 29, 2005, between Advanced Cell Technology, Inc. and Avigen
10.58 (3)	Assignment Agreement, dated December 19, 2005, by and between Genzyme Corporation and Avigen
10.59 (3)	License Agreement, dated January 12, 2006, by and between SDI Diagnostics International LTD, a division of Sanochemia Pharmazeutika AG, and Avigen
10.60 (2)	Separation Agreement, dated January 6, 2006, between Avigen and Thomas J. Paulson, together with Amendment No. 1 thereto dated February 3, 2006.
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature pages hereto)
31.1	CEO Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	CFO Certification required by Rule 13a-14(a) or Rule 15d-14(a)
32.1(19)	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)

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**Keys to Exhibits:**

- (1) Filed as an exhibit to the Registrant's Registration Statement on Form S-1 (No. 333-03220) and incorporated herein by reference.
- (2) Management Contract or Compensation Plan.
- (3) Confidential treatment has been requested for portions of this exhibit.
- (4) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Annual Report on Form 10-K for the year ended June 30, 1999, as filed with the SEC (Commission File No. 000-28272).
- (5) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Registration Statement on Form S-8 (Registration No. 333-42210) filed with the SEC on July 25, 2000.
- (6) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Annual Report on Form 10-K for the year ended June 30, 1997, as filed with the SEC (Commission File No. 000-28272).
- (8) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Current Report on Form 8-K filed with the SEC on May 31, 2005 (Commission File No. 000-28272).
- (10) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000, as filed with the SEC (Commission File No. 000-28272).
- (11) Portions of this exhibit have been omitted pursuant to a grant of confidential treatment.
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- (17) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Registration Statement on Form S-8 (Registration No. 333-90504) filed with the SEC on June 14, 2002.
- (19) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Avigen under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.
- (20) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as filed with the SEC (Commission File No. 000-28272).
- (21) Incorporated by reference from the disclosure contained in Item 1.01 of Avigen's Current Report on Form 8-K filed with the SEC on February 21, 2006 discussing such compensation (Commission File No. 000-28272).
- (22) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, as filed with the SEC (Commission File No. 000-28272).
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## SIGNATURES

Pursuant to the requirements of Section 13 of 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AVIGEN, INC.

By: /s/ KENNETH G. CHAHINE  
Kenneth G. Chahine, J.D., Ph.D.  
*President and Chief Executive Officer*

Dated: March 14, 2006

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kenneth Chahine and Andrew A. Sauter, and each or any one of them, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ KENNETH G. CHAHINE</u> Kenneth G. Chahine, J.D., Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2006
<u>/s/ ANDREW A. SAUTER</u> Andrew A. Sauter	Vice President, Finance (Principal Financial and Accounting Officer)	March 14, 2006
<u>/s/ ZOLA HOROVITZ,</u> Zola Horovitz, Ph.D.	Chairman of the Board	March 14, 2006
<u>/s/ YUICHI IWAKI</u> Yuichi Iwaki, M.D., Ph.D.	Director	March 14, 2006
<u>/s/ JOHN K.A. PRENDERGAST</u> John K.A. Prendergast, Ph.D.	Director	March 14, 2006
<u>/s/ DANIEL VAPNEK</u> Daniel Vapnek, Ph.D.	Director	March 14, 2006

## EXHIBIT INDEX

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- (19) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Avigen under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.
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**EXHIBIT 23.1**

**CONSENT OF INDEPENDENT PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Reg. Nos. 333-12087, 333-68637, 333-94111, 333-42210, 333-56274, 333-90504 and 333-116740) pertaining to the 1993 Stock Option Plan, the 1996 Equity Incentive Plan, the 1996 Non-Employee Directors' Stock Option Plan, the 1997 Employee Stock Purchase Plan, and the 2000 Equity Incentive Plan, and Registration Statements on Form S-3 (Reg. Nos. 333-68117, 333-72225, 333-79925, 333-92355 and 333-47680) and in the related Prospectuses of Avigen, Inc. of our reports dated March 14, 2006, with respect to the financial statements of Avigen, Inc., Avigen, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Avigen, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2005.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 14, 2006

## CERTIFICATION

I, Kenneth Chahine, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avigen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2006

/s/ KENNETH G. CHAHINE

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Kenneth G. Chahine  
*Chief Executive Officer and President*  
 (Principal Executive Officer)

## CERTIFICATION

I, Andrew A. Sauter, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avigen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2006

/s/ ANDREW A. SAUTER

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Andrew A. Sauter  
Vice President, Finance  
(Principal Financial Officer)

**EXHIBIT 32.1**

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Kenneth Chahine, Chief Executive Officer of Avigen, Inc. (the "Company"), and Thomas J. Paulson, Chief Financial Officer of the Company, each hereby certify that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2005, and to which this Certification is attached as Exhibit 32.1, (the "Periodic Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**In Witness Whereof**, the undersigned have set their hands hereto as of the 14th day of March, 2006.

/s/ KENNETH G. CHAHINE

Kenneth G. Chahine  
*Chief Executive Officer*

/s/ ANDREW A. SAUTER

Andrew A. Sauter  
*Vice President, Finance*

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## CORPORATE INFORMATION

### CORPORATE HEADQUARTERS

1301 Harbor Bay Parkway  
Alameda, CA 94502  
(510) 748-7150 telephone  
(510) 748-7155 facsimile

### LEGAL COUNSEL

Cooley Godward LLP  
Palo Alto, CA

### INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP  
Palo Alto, CA

### TRANSFER AGENT & REGISTRAR

Stockholders with questions regarding stock transfer requirements, lost certificates, and changes of address should contact our Transfer Agent:

American Stock Transfer &  
Trust Company  
59 Maiden Lane  
New York, NY 10038  
(800) 937-5449

### INVESTOR RELATIONS

For additional information about Avigen, please see our web site at [www.avigen.com](http://www.avigen.com). Investor inquiries and requests for additional copies of this report, free of charge, should be directed to Investor Relations at (510) 748-7372 or via e-mail at [ir@avigen.com](mailto:ir@avigen.com).

### COMMON STOCK INFORMATION

The Company's common stock is traded on the NASDAQ National Market under the symbol AVGN. As of April 5, 2006, there were approximately 126 stockholders of record of the Company's common stock and 20,949,677 shares of common stock outstanding.

Avigen has not paid dividends on its common stock since its inception, and does not anticipate paying any dividends for the foreseeable future.

### ANNUAL MEETING

The Annual Meeting of stockholders will be held on Wednesday, May 31, 2006, at 10:00 a.m. local time at the Benjamin Hotel at 125 East 50<sup>th</sup> Street, New York, NY, in the Morrison Room, 2<sup>nd</sup> Floor.

### STOCKHOLDER COMMUNICATIONS WITH THE BOARD OF DIRECTORS

Stockholders who wish to communicate with the board or an individual director may send a written communication addressed as follows:

Avigen Board Communication  
1301 Harbor Bay Parkway  
Alameda, CA 94502

Or send by e-mail to: [board@avigen.com](mailto:board@avigen.com).

## BOARD OF DIRECTORS

**Zola Horovitz, PhD (1, 2, 3)**

Chairman of the Board  
Pharmaceutical Consultant,  
Former Vice President, Business Development  
and Planning, Bristol-Myers Squibb Co.

**John Prendergast, PhD (1, 2, 3)**

Lead Independent Director  
President, SummerCloud Bay, Inc.

**Daniel Vapnek, PhD (1, 3)**

Adjunct Professor, University of California,  
Santa Barbara  
Former Senior Vice President of Research,  
Amgen, Inc.

**Kenneth Chahine, PhD, JD**

President, Chief Executive Officer

**Yuichi Iwaki, MD, PhD (1, 2)**

Professor of Urology, Pathology and Surgery,  
Director of Transplantation Immunology Laboratory,  
University of Southern California  
School of Medicine

**Richard Wallace, BCom**

Senior Vice President, Global Commercial Strategy,  
GlaxoSmithKline

(1) Governance and Nominating Committee

(2) Audit Committee

(3) Compensation Committee

## OFFICERS



**Kenneth Chahine, PhD, JD**

President,  
Chief Executive Officer



**Michael Coffee**

Chief Business Officer



**Kirk Johnson, PhD**

Vice President,  
Preclinical Development



**Andrew Sauter**

Vice President, Finance



**M. Christina Thomson, JD**

Vice President,  
Corporate Counsel



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